FORM PTO-1390 (REV 10-95) U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE

TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A FILING UNDER 35 U.S.C. 371

ATTORNEY'S DOCKET NUMBER	U.S. APPLICATION NO. (If known, see 37 CFR 1.5)
Beiersdorf 454-KGB	08/930235

INTERNATIONAL APPLICATION NO.	INTERNATIONAL FILING DATE	PRIORITY DATE CLAIMED
PCT/EP96/00968	7.March 1996 (07.03.96)	15 March 1995

TITLE OF INVENTION
COSMETIC OR PHARMACEUTICAL MICROEMULSIONS

APPLICANT(S) FOR DO/EO/US
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Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. [X] This is a **FIRST** submission of items concerning a filing under 35 U.S.C. 371.
2. [ ] This is a **SECOND** or **SUBSEQUENT** submission of items concerning a filing under 35 U.S.C. 371.
3. [X] This express request to begin national examination procedures (35 U.S.C. 371(f)) at any time rather than delay examination until the expiration of the applicable time limit set in 35 U.S.C. 371(b) and PCT Articles 22 and 39(1).
4. [X] A proper Demand for International Preliminary Examination was made by the 19th month from the earliest claimed priority date.
5. [X] A copy of the International Application as filed (35 U.S.C. 371(c)(2))
   a. [ ] is transmitted herewith (required only if not transmitted by the International Bureau).
   b. [X] has been transmitted by the International Bureau.
   c. [ ] is not required, as the application was filed in the United States Receiving Office (RO/US).
6. [X] A translation of the International Application into English (35 U.S.C. 371(c)(2)).
7. [ ] Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3))
   a. [ ] are transmitted herewith (required only if not transmitted by the International Bureau).
   b. [ ] have been transmitted by the International Bureau.
   c. [ ] have not been made; however, the time limit for making such amendemnts has NOT expired.
   d. [ ] have not been made and will not be made.
8. [ ] A translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).
9. [ ] An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).
10. [ ] A translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).

Items 11. to 16. below concern document(s) or information included:

11. [ ] An Information Disclosure Statement under 37 CFR 1.97 and 1.98.
12. [ ] An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
13. [ ] A FIRST preliminary amendment.
    [ ] A SECOND or SUBSEQUENT preliminary amendment.
14. [ ] A substitute specification.
15. [ ] A change of power of attorney and/or address letter.
16. [X] Other items or information:
    COPY OF PUBLISHED APPLICATION WO 96/28131 (FIRST PAGE ONLY) (IN GERMAN)
    4 SHEETS OF DRAWINGS

U.S. APPLICATION NO (if known, see 37 CFR 1.5)	INTERNATIONAL APPLICATION NO	ATTORNEY'S DOCKET NUMBER
	PCT/EP96/00968	Beiersdorf 454-KGB

17. [X] The following fees are submitted:		CALCULATIONS PTO USE ONLY
BASIC NATIONAL FEE (37 CFR 1.492 (a) (1) - (5)):		
Search Report has been prepared by the EPO or JPO	$910.00	
International preliminary examination fee paid to USPTO (37 CFR 1.482)	$700.00	
No international preliminary examination fee paid to USPTO (37 CFR 1.482) but international search fee paid to USPTO (37 CFR 1.445(a)(2))	$770.00	
Neither international preliminary examination fee (37 CFR 1.482) nor international search fee (37 CFR 1.445(a)(2)) paid to USPTO	$1040.00	
International preliminary examination fee paid to USPTO (37 CFR 1.482) and all claims satisfied provisions of PCT Article 33(2)-(4)	$96.00	
ENTER APPROPRIATE BASIC FEE AMOUNT =		$ 910.00
Surcharge of **$130.00** for furnishing the oath or declaration later than [ ] 20 [ ] 30 months from the earliest claimed priority date (37 CFR 1.492(e)).		$

CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE	
Total claims	4 - 20 =	0	X $22.00	$
Independent claims	2 - 3 =	0	X $80.00	$
MULTIPLE DEPENDENT CLAIM(S) (if applicable)			+ $260.00	$
	TOTAL OF ABOVE CALCULATIONS =			$ -
Reduction of 1/2 for filing by small entity, if applicable. Verified Small Entity Statement must also by filed (Note 37 CFR 1.9, 1.27, 1.28).				$
	SUBTOTAL =			$ -
Processing fee of **$130.00** for furnishing the English translation later than [ ] 20 [ ] 30 months from the earliest claimed priority date (37 CFR 1.492(f)).			+	$
	TOTAL NATIONAL FEE =			$
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). $40.00 per property			+	$
	TOTAL FEES ENCLOSED =			$ -

Amount to be: refunded	$
charged	$ 910.00

a. [ ] A check in the amount of $_____ to cover the above fees is enclosed.

b. [X] Please charge my Deposit Account No. 19-3869 in the amount of $ 910.00 to cover the above fees
A duplicate copy of this sheet is enclosed

c. [X] The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 19-3869 A duplicate copy of this sheet is enclosed.

NOTE: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the application to pending status.

SEND ALL CORRESPONDENCE TO

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Description

Cosmetic or pharmaceutical microemulsions

The present invention relates to microemulsions of the oil-in-water type, to processes for their preparation and to their use for cosmetic purposes.

In one particular embodiment the present invention relates to the use of microemulsions according to the invention for medicinal purposes, especially as drug vehicles for lipophilic active substances, and to their pharmaceutical use as topical skin remedies, as well as for the parenteral administration of pharmaceutical active substances and for parenteral nutrition.

Cosmetic skin care is to be understood primarily as meaning that the natural function of the skin as a barrier to environmental influences (e.g. dirt, chemicals, microorganisms) and to the loss of endogenous substances (e.g. water, natural sebaceous substances, electrolytes) is reinforced or restored.

Impairment of this function can lead to the increased absorption of toxic or allergenic substances or to attack by microorganisms and consequently to toxic or allergic skin reactions.

A further aim of skin care is to compensate the skin's loss of sebaceous substances and water caused by daily washing. This is particularly important when the natural regenerative capacity is inadequate. Skin care products should also protect from environmental influences, especially sun and wind, and delay skin ageing.

Medicinal compositions normally contain an effective concentration of one or more drugs. For the sake of simplicity, reference is made to the legal provisions of the Federal Republic of Germany (e.g. Cosmetics

Regulations, Food and Drugs Act) for a clear distinction between cosmetic and medicinal use and corresponding products.

Common forms of cosmetic or dermatological preparations are finely disperse multiphase systems comprising one or more fat or oil phases together with one or more aqueous phases. Actual emulsions are in turn the most widespread of these systems.

Simple emulsions consist of a first phase in which droplets of a second phase (water droplets in W/O emulsions or lipid vesicles in O/W emulsions), surrounded by a shell of emulsifier, are finely dispersed. The droplet diameters of ordinary emulsions are in the range from ca. 1 μm to ca. 50 μm. Such "macroemulsions" are milky-white, unless other colouring additives are present, and opaque. Finer "macroemulsions", whose droplet diameters are in the range from ca. 10^{-1} μm to ca. 1 μm, are bluish-white, again unless colouring additives are present, and opaque.

A clear and transparent appearance is reserved for micellar and molecular solutions with particle diameters smaller than ca. 10^{-2} μm.

The particle diameter of transparent or translucent microemulsions, on the other hand, is in the range from about 10^{-2} μm to about 10^{-1} μm. Such microemulsions usually have a low viscosity. The viscosity of many microemulsions of the O/W type is comparable to that of water.

The advantage of microemulsions is that active substances can be more finely dispersed in their disperse phase than in the disperse phase of "macroemulsions". Another advantage is that their low viscosity enables them to be sprayed. When microemulsions are used as cosmetics, corresponding products are distinguished by a high cosmetic elegance.

The disadvantage of the microemulsions of the state of the art is that it is always necessary to use a high content of one or more emulsifiers because the small droplet size creates a large interface between the

phases, which normally has to be stabilized by emulsifiers.

Although the conventional cosmetic emulsifiers are safe to use per se, emulsifiers, like every other chemical substance, are capable in individual cases of causing allergic reactions or reactions based on the user's hypersensitivity.

Thus it is known that specific forms of photodermatosis are triggered by certain emulsifiers, as well as by various fats, and simultaneous exposure to sunlight. Such forms of photodermatosis are also called "Mallorca acne". One object of the present invention was therefore to develop sunscreen products.

Thus the present invention relates, by way of particular embodiments, to cosmetic and dermatological light protection preparations, especially cosmetic and dermatological light protection preparations for skin care.

The damaging effect of the ultraviolet part of solar radiation on the skin is generally known. Whereas rays with a wavelength of less than 290 nm (the so-called UVC region) are absorbed by the ozone layer in the earth's atmosphere, rays in the region between 290 nm and 320 nm, the so-called UVB region, cause erythema, simple sunburn or even burns of a greater or lesser degree.

The narrower region around 308 nm is given as a maximum for the erythematous activity of sunlight.

Numerous compounds are known for providing protection against UVB radiation, said compounds usually being derivatives of 3-benzylidenecamphor, 4-aminobenzoic acid, cinnamic acid, salicylic acid, benzophenone and also 2-phenylbenzimidazole.

It is also important to have filters for the region between about 320 nm and about 400 nm, the so-called UVA region, because its rays too can cause damage. Thus it is found that UVA radiation leads to damage of the elastic and collagenous fibres of the connective tissue, causing premature ageing of the skin, and that it is to be regarded as a cause of numerous phototoxic and

photoallergic reactions. The damaging effect of UVB radiation can be reinforced by UVA radiation.

However, UV radiation can also lead to photochemical reactions, in which case the photochemical reaction products intervene in the skin's metabolism.

To prevent these reactions, antioxidants and/or free radical scavengers can additionally be incorporated into the cosmetic or dermatological formulations.

UV absorbers or UV reflectors are mostly inorganic pigments, which are used in known manner in cosmetics for protecting the skin from UV rays. Said inorganic pigments are oxides of titanium, zinc, iron, zirconium, silicon, manganese, aluminium and cerium and mixtures thereof, as well as modifications.

Because of their good sprayability, microemulsions are also suitable for other cosmetic or dermatological applications, for example deodorants, so in one particular embodiment the present invention relates to microemulsions as a base for cosmetic deodorants.

The purpose of cosmetic deodorants is to eliminate the body odour which arises when fresh perspiration, which is odourless per se, is decomposed by micro-organisms. The conventional cosmetic deodorants are based on various principles of action.

In so-called antiperspirants, astringents - predominantly aluminium salts such as aluminium hydroxychloride (aluminium chlorhydrate) - can reduce the formation of perspiration.

The bacterial flora on the skin can be reduced by using antimicrobial substances in cosmetic deodorants. Ideally only the microorganisms which cause odour should be actively reduced here. The flow of perspiration itself is not influenced thereby and ideally only the microbial decomposition of the perspiration is temporarily stopped.

It is also common to combine astringents with antimicrobially active substances in one and the same composition.

Deodorants should satisfy the following conditions:

1) They should effect reliable deodorization.
2) The skin's natural biological processes should not be impaired by the deodorants.
3) The deodorants must be harmless when an overdose is applied or the directions for use are otherwise ignored.
4) They should not accumulate on the skin after repeated application.
5) They should be easy to incorporate into conventional cosmetic formulations.

It is known and customary to use both liquid deodorants, for example aerosol sprays, roll-ons and the like, and solid preparations, for example deodorant sticks, powders, powder sprays, cleansing agents for intimate hygiene, etc.

It is also known to use microemulsions as a base for deodorant preparations or preparations with an antiperspirant action. Their relatively high content of emulsifiers, with the disadvantages described, has so far been an obstacle which has had to be overcome.

A further object of the present invention was thus to develop preparations which are suitable as a base for cosmetic deodorants or antiperspirants and do not have the disadvantages of the state of the art.

A further object of the invention was to develop cosmetic bases for cosmetic deodorants which are distinguished by a good skin compatibility.

A further object of the present invention was to provide products based on microemulsions with the widest possible variety of applications. For example, bases should be created for forms of preparation such as cleansing emulsions and face and body care preparations, but also definitely medicinal/pharmaceutical forms of administration, for example preparations for combating acne and other abnormal skin conditions.

In one particular embodiment the invention therefore relates to cleansing emulsions, especially face cleansing emulsions and preferably make-up removers, for example eye make-up removers.

Such preparations are known per se. Conventionally they are mixtures of cosmetic oils or aqueous preparations of surface-active substances whose function is to solubilize the dirt or make-up product and remove it from the skin.

Water-resistant eye make-up, for example mascara, can be satisfactorily removed with water-based make-up removers only if special surfactants are present. However, these surfactants often have only a limited physiological compatibility. When such substances come into contact with the mucosa, especially the eye mucosa, they lead to irritation, which manifests itself for example in a reddening of the eyes. Reactions of this type are typical of products containing surfactants.

One object of the present invention was therefore to remedy such problems.

In another embodiment the present invention relates to cosmetic hair preparations. The present invention relates especially to cosmetic hair preparations for hair and scalp care. In one preferred embodiment the present invention relates to preparations whose purpose is to strengthen the individual hairs and/or give the overall hair style hold and body.

As a rough generalization, human hair can be subdivided into the living part, which is the root, and the dead part, which is the shaft. The hair shaft in turn consists of the medulla - although in the course of evolution this has regressed and become unimportant for modern man and is often totally absent in thin hair - the cortex surrounding the medulla and the cuticle investing the medulla and cortex together.

Especially the cuticle, but also the keratinous region between the cuticle and the cortex as the outer layer of the hair, are subject to particular stress due to environmental influences, due to combing and brushing and also due to hair treatment, especially hair dyeing and hair shaping, e.g. perming processes.

In cases of particularly aggressive stress, for example bleaching with oxidizing agents like hydrogen

peroxide, where the pigments distributed in the cortex are oxidatively destroyed, the inside of the hair can be detrimentally affected as well. If human hair is continually dyed, only oxidizing hair dyeing processes are suitable in practice. In oxidative hair dyeing, the dyestuff chromophore is formed by the reaction of precursors (phenols, aminophenols, more rarely also diamines) and bases (usually p-phenylenediamine) with the oxidizing agent, usually hydrogen peroxide. The hydrogen peroxide concentrations used are normally around 6%.

Conventionally it is assumed that the dyeing effect is accompanied by a bleaching effect due to the hydrogen peroxide. In oxidatively dyed human hair, in a similar way to bleached hair, microscopic holes are detectable at the sites previously occupied by melanin granules. The fact is that the oxidizing agent, hydrogen peroxide, can react not only with the dyestuff precursors but also with the substance of the hair and thus can damage the hair under certain circumstances.

Even washing the hair with aggressive surfactants can stress the hair and can at least impair its appearance or the appearance of the hair style as a whole. For example, certain water-soluble hair components (e.g. urea, uric acid, xanthine, keratin, glycogen, citric acid, lactic acid) can be extracted by washing.

For these reasons the hair care cosmetics which have been in use for some time are on the one hand those which are intended to be rinsed out of the hair after they have taken effect, and on the other hand those which are meant to remain on the hair. The latter can be formulated in such a way that they not only treat the individual hairs but also improve the appearance of the hair style as a whole, for example by giving the hair more body, holding the hair style for a longer period of time or improving the hair's stylability.

Quaternary ammonium compounds, for example, can decisively improve the hair's combability. Such compounds are adsorbed on the hair and can often be detected

on the hair even after several washes.

However, the state of the art has left a need for active substances and preparations which can satisfactorily treat damaged hair. Preparations which are intended to give body to the hair style have also often proved unsatisfactory, at least being unsuitable for use as hair care preparations. Preparations of the state of the art for holding the hair style normally contain viscous components, for example; these run the risk of creating a sticky feel which often has to be compensated by skilful formulation.

The object was therefore also to remedy these disadvantages of the state of the art.

Finally, the present invention should also basically provide emulsions for internal use, for example for the parenteral administration of pharmaceutical active substances and for parenteral nutrition.

One particular object of the present invention was to provide finely disperse preparations of the oil-in-water type with the lowest possible emulsifier content, which do not have the disadvantages of the state of the art and which are suitable for a very wide variety of cosmetic and/or dermatological applications, for example the uses described above. Another object of the invention was to enlarge the limited range of finely disperse preparations of the oil-in-water type of the state of the art.

It is known per se that hydrophilic emulsifiers, namely polyethoxylated and polypropoxylated emulsifiers, change their solubility properties from water-soluble to fat-soluble as the temperature increases. One characteristic of the hydrophilicity of a given emulsifier is its HLB value.

The HLB value of polyol fatty acid esters is defined by the relationship

$$HLB = 20 * (1 - S/A) \quad \text{(formula I)}$$

The following relationship applies to a group of emulsifiers whose hydrophilic part consists only of ethylene oxide units:

$$HLB = E/5 \qquad \text{(formula II)}$$

where S = saponification number of the ester

A = acid number of the recovered acid

E = proportion by weight of ethylene oxide (in %) in the total molecule.

Emulsifiers with HLB values of 6-8 are generally W/O emulsifiers and those with HLB values of 8-18 are generally O/W emulsifiers.

Literature: "Kosmetik - Entwicklung, Herstellung und Anwendung kosmetischer Mittel" ("Cosmetics - Development, Manufacture and Use of Cosmetic Compositions"); W. Umbach (ed.), Georg Thieme Verlag 1988.

The temperature range in which the emulsifiers change their solubility is called the phase inversion temperature range. The abbreviation "PIT" will also be used for the phase inversion temperature range in the present specification.

The change in these solubility properties manifests itself in known manner as follows: A mixture of water, oil and O/W emulsifiers which gives an O/W emulsion below the PIT, after stirring, is brought to a temperature above the PIT, typically about 70-90°C; it can pass through an intermediate microemulsion stage and finally gives a W/O emulsion above the PIT. If this emulsion is cooled, an O/W emulsion is again obtained although it has a droplet size of up to 200 nm, placing it in the region between a microemulsion and a fine macroemulsion.

However, microemulsions of the state of the art which are prepared in this way have the disadvantage that firstly the droplet size is still very large, the emulsion is white to bluish in colour and opaque at room temperature, and/or it is still necessary to have a high proportion of one or more emulsifiers.

Another disadvantage is that although microemulsions prepared in this way can be practically transparent at high temperature, i.e. in the PIT, for example, they become opaque again on cooling to room temperature.

Thus these obstacles also had to be overcome.

Surprisingly, all these objects are achieved by

transparent or translucent microemulsions of the oil-in-water type

- comprising an oil phase, composed essentially of constituents of low volatility, and an aqueous phase
- containing:
  one or more polyethoxylated O/W emulsifiers and/or one or more polypropoxylated O/W emulsifiers and/or one or more polyethoxylated and polypropoxylated O/W emulsifiers,
- and also containing one or more W/O emulsifiers, if desired,
- having an emulsifier content of less than 20% by weight, based on the total weight of the emulsion,
- and obtainable by a process in which a mixture of the base components, comprising the aqueous phase, the oil phase, one or more of the O/W emulsifiers according to the invention, one or more W/O emulsifiers, if desired, and other auxiliary substances, additives and/or active substances, if desired, is brought to a temperature within or above the phase inversion temperature range and then cooled to room temperature.

Microemulsions according to the invention have a low viscosity, are sprayable, are outstandingly suitable as vehicles for a very wide variety of active substances, especially lipid-soluble active substances, and are also distinguished by an excellent compatibility with the skin and mucosa.

Although JP-A-Hei-06/262060 (according to Patent Abstracts of Japan) has described a solubilized preparation which can comprise polyethylene glycol alkyl ethers, for example, the oil phase of the disclosed Examples consists of the highly volatile heptane, which can scarcely be commonly regarded as an oil component and even less as a cosmetic or pharmaceutical oil component. Despite the claim made, the microemulsions produced according to said teaching cannot be regarded as cosmetics or pharmaceuticals.

US-A-4,146,499 has furthermore described micro-

emulsions which contain ethoxylated raw materials, but their oil phase typically consists of such unphysiological constituents as benzene, carbon tetrachloride, dichloromethane and chlorofluorocarbons. Consequently said document of the state of the art was also incapable of anticipating the present invention.

The polyethoxylated or polypropoxylated or polyethoxylated and polypropoxylated O/W emulsifier or emulsifiers are advantageously selected from the group comprising

- fatty alcohol ethoxylates of the general formula $R\text{-}O\text{-}(\text{-}CH_2\text{-}CH_2\text{-}O\text{-})_n\text{-}H$, in which R is a branched or unbranched alkyl, aryl or alkenyl radical and n is a number from 10 to 50,
- ethoxylated wool wax alcohols,
- polyethylene glycol ethers of the general formula $R\text{-}O\text{-}(\text{-}CH_2\text{-}CH_2\text{-}O\text{-})_n\text{-}R'$, in which R and R' independently of one another are branched or unbranched alkyl or alkenyl radicals and n is a number from 10 to 80,
- fatty acid ethoxylates of the general formula $R\text{-}COO\text{-}(\text{-}CH_2\text{-}CH_2\text{-}O\text{-})_n\text{-}H$, in which R is a branched or unbranched alkyl or alkenyl radical and n is a number from 10 to 40,
- etherified fatty acid ethoxylates of the general formula $R\text{-}COO\text{-}(\text{-}CH_2\text{-}CH_2\text{-}O\text{-})_n\text{-}R'$, in which R and R' independently of one another are branched or unbranched alkyl or alkenyl radicals and n is a number from 10 to 80,
- esterified fatty acid ethoxylates of the general formula $R\text{-}COO\text{-}(\text{-}CH_2\text{-}CH_2\text{-}O\text{-})_n\text{-}C(O)\text{-}R'$, in which R and R' independently of one another are branched or unbranched alkyl or alkenyl radicals and n is a number from 10 to 80,
- polyethylene glycol glycerol fatty acid esters of saturated and/or unsaturated, branched and/or unbranched fatty acids, with a degree of ethoxylation of between 3 and 50,
- ethoxylated sorbitan esters with a degree of

ethoxylation of 3 to 100,

- cholesterol ethoxylates with a degree of ethoxylation of between 3 and 50,
- ethoxylated triglycerides with a degree of ethoxylation of between 3 and 150,
- alkyl ether carboxylic acids of the general formula $R-O-(-CH_2-CH_2-O-)_n-CH_2-COOH$ or their cosmetically or pharmaceutically acceptable salts, in which R is a branched or unbranched alkyl or alkenyl radical having 5 - 30 C atoms and n is a number from 5 to 30,
- polyoxyethylene sorbitol fatty acid esters based on branched or unbranched alkanoic or alkenoic acids and having a degree of ethoxylation of 5 to 100, for example of the sorbeth type,
- alkyl ether sulphates or the acids on which these sulphates are based, of the general formula $R-O-(-CH_2-CH_2-O-)_n-SO_3-H$, with cosmetically or pharmaceutically acceptable cations, in which R is a branched or unbranched alkyl or alkenyl radical having 5 - 30 C atoms and n is a number from 1 to 50,
- fatty alcohol propoxylates of the general formula $R-O-(-CH_2-CH(CH_3)-O-)_n-H$, in which R is a branched or unbranched alkyl or alkenyl radical and n is a number from 10 to 80,
- polypropylene glycol ethers of the general formula $R-O-(-CH_2-CH(CH_3)-O-)_n-R'$, in which R and R' independently of one another are branched or unbranched alkyl or alkenyl radicals and n is a number from 10 to 80,
- propoxylated wool wax alcohols,
- etherified fatty acid propoxylates of the general formula $R-COO-(-CH_2-CH(CH_3)-O-)_n-R'$, in which R and R' independently of one another are branched or unbranched alkyl or alkenyl radicals and n is a number from 10 to 80,
- esterified fatty acid propoxylates of the general formula $R-COO-(-CH_2-CH(CH_3)-O-)_n-C(O)-R'$, in which R

and R' independently of one another are branched or unbranched alkyl or alkenyl radicals and n is a number from 10 to 80,

- fatty acid propoxylates of the general formula $R\text{-}COO\text{-}(\text{-}CH_2\text{-}CH(CH_3)\text{-}O\text{-})_n\text{-}H$, in which R is a branched or unbranched alkyl or alkenyl radical and n is a number from 10 to 80,
- polypropylene glycol glycerol fatty acid esters of saturated and/or unsaturated, branched and/or unbranched fatty acids, with a degree of propoxylation of between 3 and 80,
- propoxylated sorbitan esters with a degree of propoxylation of 3 to 100,
- cholesterol propoxylates with a degree of propoxylation of 3 to 100,
- propoxylated triglycerides with a degree of propoxylation of 3 to 100,
- alkyl ether carboxylic acids of the general formula $R\text{-}O\text{-}(\text{-}CH_2\text{-}CH(CH_3)O\text{-})_n\text{-}CH_2\text{-}COOH$ or their cosmetically or pharmaceutically acceptable salts, in which R is a branched or unbranched alkyl or alkenyl radical and n is a number from 3 to 50,
- alkyl ether sulphates or the acids on which these sulphates are based, of the general formula $R\text{-}O\text{-}(\text{-}CH_2\text{-}CH(CH_3)\text{-}O\text{-})_n\text{-}SO_3\text{-}H$, with cosmetically or pharmaceutically acceptable cations, in which R is a branched or unbranched alkyl or alkenyl radical having 5 - 30 C atoms and n is a number from 1 to 50,
- fatty alcohol ethoxylates/propoxylates of the general formula $R\text{-}O\text{-}X_n\text{-}Y_m\text{-}H$, in which R is a branched or unbranched alkyl or alkenyl radical, X and Y are not identical and are each either an oxyethylene group or an oxypropylene group and n and m independently of one another are numbers from 5 to 50,
- polypropylene glycol ethers of the general formula $R\text{-}O\text{-}X_n\text{-}Y_m\text{-}R'$, in which R and R' independently of one another are branched or unbranched alkyl or alkenyl

radicals, X and Y are not identical and are each either an oxyethylene group or an oxypropylene group and n and m independently of one another are numbers from 5 to 100,

- etherified fatty acid propoxylates of the general formula $R\text{-}COO\text{-}X_n\text{-}Y_m\text{-}R'$, in which R and R' independently of one another are branched or unbranched alkyl or alkenyl radicals, X and Y are not identical and are each either an oxyethylene group or an oxypropylene group and n and m independently of one another are numbers from 5 to 100,
- fatty acid ethoxylates/propoxylates of the general formula $R\text{-}COO\text{-}X_n\text{-}Y_m\text{-}H$, in which R is a branched or unbranched alkyl or alkenyl radical, X and Y are not identical and are each either an oxyethylene group or an oxypropylene group and n and m independently of one another are numbers from 5 to 50.

In particular, the polyethoxylated or polypropoxylated or polyethoxylated and polypropoxylated O/W emulsifier or emulsifiers are advantageously selected from the group comprising

- fatty alcohol ethoxylates of the general formula $R\text{-}O\text{-}(\text{-}CH_2\text{-}CH_2\text{-}O\text{-})_n\text{-}H$, in which R is a branched or unbranched alkyl or alkenyl radical having 5 - 30 C atoms and n is a number from 10 to 25,
- ethoxylated wool wax alcohols with HLB values of 11 - 16, very particularly advantageously with HLB values of 14.5 - 15.5,
- polyethylene glycol ethers of the general formula $R\text{-}O\text{-}(\text{-}CH_2\text{-}CH_2\text{-}O\text{-})_n\text{-}R'$, in which R and R' independently of one another are branched or unbranched alkyl or alkenyl radicals having 5 - 30 C atoms and n is a number from 10 to 25,
- fatty acid ethoxylates of the general formula $R\text{-}COO\text{-}(\text{-}CH_2\text{-}CH_2\text{-}O\text{-})_n\text{-}H$, in which R is a branched or unbranched alkyl or alkenyl radical having 5 - 30 C atoms and n is a number from 10 to 25,
- etherified fatty acid ethoxylates of the general

formula $R\text{-}COO\text{-}(\text{-}CH_2\text{-}CH_2\text{-}O\text{-})_n\text{-}R'$, in which R and R' independently of one another are branched or unbranched alkyl or alkenyl radicals having 5 - 30 C atoms and n is a number from 10 to 50,

- esterified fatty acid ethoxylates of the general formula $R\text{-}COO\text{-}(\text{-}CH_2\text{-}CH_2\text{-}O\text{-})_n\text{-}C(O)\text{-}R'$, in which R and R' independently of one another are branched or unbranched alkyl or alkenyl radicals having 5 - 30 C atoms and n is a number from 10 to 50,
- polyethylene glycol glycerol fatty acid esters of saturated and/or unsaturated, branched and/or unbranched fatty acids having 6 to 26 C atoms and a degree of ethoxylation of between 3 and 40,
- ethoxylated sorbitan esters with a degree of ethoxylation of 3 to 30,
- cholesterol ethoxylates with HLB values of 11 - 16, very particularly advantageously with HLB values of 14.5 - 15.5,
- ethoxylated triglycerides with HLB values of 11 - 16, very particularly advantageously with HLB values of 14.5 - 15.5,
- alkyl ether carboxylic acids of the general formula $R\text{-}O\text{-}(\text{-}CH_2\text{-}CH_2\text{-}O\text{-})_n\text{-}CH_2\text{-}COOH$ or their cosmetically or pharmaceutically acceptable salts, in which R is a branched or unbranched alkyl or alkenyl radical having 5 - 30 C atoms and n is a number from 10 to 20,
- polyoxyethylene sorbitol fatty acid esters based on branched or unbranched alkanoic or alkenoic acids and having a degree of ethoxylation of 10 to 80, for example of the sorbeth type,
- alkyl ether sulphates or the acids on which these sulphates are based, of the general formula $R\text{-}O\text{-}(\text{-}CH_2\text{-}CH_2\text{-}O\text{-})_n\text{-}SO_3\text{-}H$, with cosmetically or pharmaceutically acceptable cations, in which R is a branched or unbranched alkyl or alkenyl radical having 5 - 30 C atoms and n is a number from 3 to 30,
- fatty alcohol propoxylates of the general formula

$R\text{-}O\text{-}(\text{-}CH_2\text{-}CH(CH_3)\text{-}O\text{-})_n\text{-}H$, in which R is a branched or unbranched alkyl or alkenyl radical having 5 - 30 C atoms and n is a number from 10 to 30,

- polypropylene glycol ethers of the general formula $R\text{-}O\text{-}(\text{-}CH_2\text{-}CH(CH_3)\text{-}O\text{-})_n\text{-}R'$, in which R and R' independently of one another are branched or unbranched alkyl or alkenyl radicals having 5 - 30 C atoms and n is a number from 10 to 40,
- propoxylated wool wax alcohols with HLB values of 11 - 16, very particularly advantageously with HLB values of 14.5 - 15.5,
- fatty acid propoxylates of the general formula $R\text{-}COO\text{-}(\text{-}CH_2\text{-}CH(CH_3)\text{-}O\text{-})_n\text{-}H$, in which R is a branched or unbranched alkyl or alkenyl radical having 5 - 30 C atoms and n is a number from 10 to 40,
- etherified fatty acid propoxylates of the general formula $R\text{-}COO\text{-}(\text{-}CH_2\text{-}CH(CH_3)\text{-}O\text{-})_n\text{-}R'$, in which R and R' independently of one another are branched or unbranched alkyl or alkenyl radicals having 5 - 30 C atoms and n is a number from 10 to 30,
- esterified fatty acid propoxylates of the general formula $R\text{-}COO\text{-}(\text{-}CH_2\text{-}CH(CH_3)\text{-}O\text{-})_n\text{-}C(O)\text{-}R'$, in which R and R' independently of one another are branched or unbranched alkyl or alkenyl radicals having 5 - 30 C atoms and n is a number from 10 to 50,
- polypropylene glycol glycerol fatty acid esters of saturated and/or unsaturated, branched and/or unbranched fatty acids having 6 to 26 C atoms and a degree of propoxylation of between 3 and 50,
- propoxylated sorbitan esters with a degree of propoxylation of 3 to 80,
- cholesterol propoxylates with HLB values of 11 - 16, very particularly advantageously with HLB values of 14.5 - 15.5,
- propoxylated triglycerides with HLB values of 11 - 16, very particularly advantageously with HLB values of 14.5 - 15.5,
- alkyl ether carboxylic acids of the general formula $R\text{-}O\text{-}(\text{-}CH_2\text{-}CH(CH_3)O\text{-})_n\text{-}CH_2\text{-}COOH$, or their cosmetically

or pharmaceutically acceptable salts, in which R is a branched or unbranched alkyl or alkenyl radical having 5 - 30 C atoms and n is a number from 10 to 30,

- alkyl ether sulphates or the acids on which these sulphates are based, of the general formula $R\text{-}O\text{-}(\text{-}CH_2\text{-}CH(CH_3)\text{-}O\text{-})_n\text{-}SO_3\text{-}H$, with cosmetically or pharmaceutically acceptable cations, in which R is a branched or unbranched alkyl or alkenyl radical having 5 - 30 C atoms and n is a number from 1 to 30.

According to the invention, the polyethoxylated or polypropoxylated or polyethoxylated and polypropoxylated O/W emulsifiers are particularly advantageously selected from the group of substances with HLB values of 11 - 16, very particularly advantageously from those with HLB values of 14.5 - 15.5, if the O/W emulsifiers have saturated radicals R and R'. If the O/W emulsifiers have unsaturated radicals R and/or R', or if isoalkyl derivatives are present, the preferred HLB value of such emulsifiers can also be lower or higher.

The fatty alcohol ethoxylates are advantageously selected from the group comprising ethoxylated stearyl alcohols, cetyl alcohols and cetylstearyl alcohols (cetearyl alcohols). The following are particularly preferred:
polyethylene glycol (13) stearyl ether (steareth-13), polyethylene glycol (14) stearyl ether (steareth-14), polyethylene glycol (15) stearyl ether (steareth-15), polyethylene glycol (16) stearyl ether (steareth-16), polyethylene glycol (17) stearyl ether (steareth-17), polyethylene glycol (18) stearyl ether (steareth-18), polyethylene glycol (19) stearyl ether (steareth-19), polyethylene glycol (20) stearyl ether (steareth-20), polyethylene glycol (12) isostearyl ether (isosteareth-12), polyethylene glycol (13) isostearyl ether (isosteareth-13), polyethylene glycol (14) isostearyl ether (isosteareth-14), polyethylene glycol (15) isostearyl ether (isosteareth-15), polyethylene glycol

(16) isostearyl ether (isosteareth-16), polyethylene glycol (17) isostearyl ether (isosteareth-17), polyethylene glycol (18) isostearyl ether (isosteareth-18), polyethylene glycol (19) isostearyl ether (isosteareth-19), polyethylene glycol (20) isostearyl ether (isosteareth-20),

polyethylene glycol (13) cetyl ether (ceteth-13), polyethylene glycol (14) cetyl ether (ceteth-14), polyethylene glycol (15) cetyl ether (ceteth-15), polyethylene glycol (16) cetyl ether (ceteth-16), polyethylene glycol (17) cetyl ether (ceteth-17), polyethylene glycol (18) cetyl ether (ceteth-18), polyethylene glycol (19) cetyl ether (ceteth-19), polyethylene glycol (20) cetyl ether (ceteth-20),

polyethylene glycol (13) isocetyl ether (isoceteth-13), polyethylene glycol (14) isocetyl ether (isoceteth-14), polyethylene glycol (15) isocetyl ether (isoceteth-15), polyethylene glycol (16) isocetyl ether (isoceteth-16), polyethylene glycol (17) isocetyl ether (isoceteth-17), polyethylene glycol (18) isocetyl ether (isoceteth-18), polyethylene glycol (19) isocetyl ether (isoceteth-19), polyethylene glycol (20) isocetyl ether (isoceteth-20),

polyethylene glycol (12) oleyl ether (oleth-12), polyethylene glycol (13) oleyl ether (oleth-13), polyethylene glycol (14) oleyl ether (oleth-14), polyethylene glycol (15) oleyl ether (oleth-15),

polyethylene glycol (12) lauryl ether (laureth-12), polyethylene glycol (12) isolauryl ether (isolaureth-12), polyethylene glycol (13) cetylstearyl ether (ceteareth-13), polyethylene glycol (14) cetylstearyl ether (ceteareth-14), polyethylene glycol (15) cetylstearyl ether (ceteareth-15), polyethylene glycol (16) cetylstearyl ether (ceteareth-16), polyethylene glycol (17) cetylstearyl ether (ceteareth-17), polyethylene glycol (18) cetylstearyl ether (ceteareth-18), polyethylene glycol (19) cetylstearyl ether (ceteareth-19), polyethylene glycol (20) cetylstearyl ether (ceteareth-20).

The fatty acid ethoxylates are also advantageously

selected from the following group:
polyethylene glycol (20) stearate, polyethylene glycol (21) stearate, polyethylene glycol (22) stearate, polyethylene glycol (23) stearate, polyethylene glycol (24) stearate, polyethylene glycol (25) stearate,
polyethylene glycol (12) isostearate, polyethylene glycol (13) isostearate, polyethylene glycol (14) isostearate, polyethylene glycol (15) isostearate, polyethylene glycol (16) isostearate, polyethylene glycol (17) isostearate, polyethylene glycol (18) isostearate, polyethylene glycol (19) isostearate, polyethylene glycol (20) isostearate, polyethylene glycol (21) isostearate, polyethylene glycol (22) isostearate, polyethylene glycol (23) isostearate, polyethylene glycol (24) isostearate, polyethylene glycol (25) isostearate,
polyethylene glycol (12) oleate, polyethylene glycol (13) oleate, polyethylene glycol (14) oleate, polyethylene glycol (15) oleate, polyethylene glycol (16) oleate, polyethylene glycol (17) oleate, polyethylene glycol (18) oleate, polyethylene glycol (19) oleate, polyethylene glycol (20) oleate.

Sodium laureth-11 carboxylate can advantageously be used as the ethoxylated alkyl ether carboxylic acid or its salt.

Sodium laureth-1-4 sulphate can advantageously be used as the alkyl ether sulphate.

Polyethylene glycol (30) cholesteryl ether can advantageously be used as the ethoxylated cholesterol derivative. Polyethylene glycol (25) soya sterol has also proved satisfactory.

Polyethylene glycol (60) evening primrose glycerides can advantageously be used as ethoxylated triglycerides.

Furthermore, the polyethylene glycol glycerol fatty acid esters are advantageously selected from the group comprising polyethylene glycol (20) glyceryl laurate, polyethylene glycol (21) glyceryl laurate, polyethylene glycol (22) glyceryl laurate, polyethylene glycol (23) glyceryl laurate, polyethylene glycol (6) glyceryl caprylate/caprate, polyethylene glycol (20) glyceryl

oleate, polyethylene glycol (20) glyceryl isostearate, polyethylene glycol (18) glyceryl oleate/cocoate.

It is also favourable to select the sorbitan esters from the group comprising polyethylene glycol (20) sorbitan monolaurate, polyethylene glycol (20) sorbitan monostearate, polyethylene glycol (20) sorbitan monoisostearate, polyethylene glycol (20) sorbitan monopalmitate, polyethylene glycol (20) sorbitan monooleate.

The following can be used as W/O emulsifiers which are optional but nevertheless advantageous according to the invention: fatty alcohols having 8 to 30 carbon atoms, monoglycerol esters of saturated and/or unsaturated, branched and/or unbranched alkanecarboxylic acids with a chain length of 8 to 24 C atoms, especially 12 - 18 C atoms, diglycerol esters of saturated and/or unsaturated, branched and/or unbranched alkanecarboxylic acids with a chain length of 8 to 24 C atoms, especially 12 - 18 C atoms, monoglycerol ethers of saturated and/or unsaturated, branched and/or unbranched alcohols with a chain length of 8 to 24 C atoms, especially 12 - 18 C atoms, diglycerol ethers of saturated and/or unsaturated, branched and/or unbranched alcohols with a chain length of 8 to 24 C atoms, especially 12 - 18 C atoms, propylene glycol esters of saturated and/or unsaturated, branched and/or unbranched alkanecarboxylic acids with a chain length of 8 to 24 C atoms, especially 12 - 18 C atoms, and sorbitan esters of saturated and/or unsaturated, branched and/or unbranched alkanecarboxylic acids with a chain length of 8 to 24 C atoms, especially 12 - 18 C atoms.

Particularly advantageous W/O emulsifiers are glyceryl monostearate, glyceryl monoisostearate, glyceryl monomyristate, glyceryl monooleate, diglyceryl monostearate, diglyceryl monoisostearate, propylene glycol monostearate, propylene glycol monoisostearate, propylene glycol monocaprylate, propylene glycol monolaurate, sorbitan monoisostearate, sorbitan monolaurate, sorbitan monocaprylate, sorbitan monoisooleate, sucrose

distearate, cetyl alcohol, stearyl alcohol, arachidyl alcohol, behenyl alcohol, isobehenyl alcohol, selachyl alcohol, chimyl alcohol, polyethylene glycol (2) stearyl ether (steareth-2), glyceryl monolaurate, glyceryl monocaprate and glyceryl monocaprylate.

It is possible according to the invention to keep the total content of emulsifiers below 15% by weight, based on the total weight of the microemulsion. The total content of emulsifiers is preferably kept below 10% by weight, especially below 8% by weight, based on the total weight of the microemulsion.

The oil phase of the microemulsions according to the invention is advantageously selected from the group comprising esters of saturated and/or unsaturated, branched and/or unbranched alkanecarboxylic acids with a chain length of 3 to 30 C atoms and saturated and/or unsaturated, branched and/or unbranched alcohols with a chain length of 3 to 30 C atoms, and from the group comprising esters of aromatic carboxylic acids and saturated and/or unsaturated, branched and/or unbranched alcohols with a chain length of 3 to 30 C atoms. Such ester oils can then advantageously be selected from the group comprising isopropyl myristate, isopropyl palmitate, isopropyl stearate, isopropyl oleate, n-butyl stearate, n-hexyl laurate, n-decyl oleate, isooctyl stearate, isononyl stearate, isononyl isononanoate, 2-ethylhexyl palmitate, 2-ethylhexyl laurate, 2-hexyldecyl stearate, 2-octyldodecyl palmitate, oleyl oleate, oleyl erucate, erucyl oleate, erucyl erucate and synthetic, semisynthetic and natural mixtures of such esters, e.g. jojoba oil.

The oil phase can also advantageously be selected from the group comprising branched and unbranched hydrocarbons and hydrocarbon waxes, silicone oils and dialkyl ethers, from the group comprising saturated or unsaturated, branched or unbranched alcohols, and from fatty acid triglycerides, namely the triglycerol esters of saturated and/or unsaturated, branched and/or unbranched alkanecarboxylic acids with a chain length of

8 to 24 C atoms, especially 12 - 18 C atoms. The fatty acid triglycerides can advantageously be selected for example from the group comprising synthetic, semi-synthetic and natural oils, e.g. olive oil, sunflower oil, soya oil, groundnut oil, rapeseed oil, almond oil, palm oil, coconut oil, palm kernel oil, etc.

Arbitrary mixtures of such oil and wax components can also advantageously be used in terms of the present invention.

It may also be advantageous to use waxes, for example cetyl palmitate, as the only lipid component of the oil phase. In such cases the O/W microemulsions according to the invention may also be obtained as microdispersions of solid wax particles.

The oil phase is advantageously selected from the group comprising 2-ethylhexyl isostearate, octyldodecanol, isotridecyl isononanoate, isoeicosane, 2-ethylhexyl cocoate, C_{12-15}-alkyl benzoate, caprylic/ capric triglyceride and dicaprylyl ether.

Mixtures of C_{12-15}-alkyl benzoate and 2-ethylhexyl isostearate, mixtures of C_{12-15}-alkyl benzoate and isotridecyl isononanoate and mixtures of C_{12-15}-alkyl benzoate, 2-ethylhexyl isostearate and isotridecyl isononanoate are particularly advantageous.

Of the hydrocarbons, paraffin oil, squalane and squalene can advantageously be used in terms of the present invention.

The oil phase can advantageously also contain cyclic or linear silicone oils or can consist entirely of such oils, although it is preferable for the oil phase to contain other oil phase components in addition to the silicone oil or silicone oils.

The silicone oil to be used according to the invention is advantageously cyclomethicone (octamethylcyclotetrasiloxane). However, the use of other silicone oils, for example hexamethylcyclotrisiloxane, polydimethylsiloxane and poly(methylphenylsiloxane), is also advantageous in terms of the present invention.

Mixtures of cyclomethicone and isotridecyl

isononanoate and mixtures of cyclomethicone and 2-ethylhexyl isostearate are also particularly advantageous.

The microemulsions according to the invention are advantageously prepared by a process in which a mixture of the base components, comprising the aqueous phase, the oil phase, one or more of the O/W emulsifiers according to the invention, one or more W/O emulsifiers, if desired, and other auxiliary substances, additives and/or active substances which form an O/W emulsion below the phase inversion temperature range, if desired, is brought to a temperature above or within the phase inversion temperature range and the microemulsion formed is then cooled to room temperature. This is preferably carried out with stirring.

Surprisingly it is always possible to dispense with a homogenization step.

A process for the preparation of O/W microemulsions which comprise:

(1) an aqueous phase comprising, if desired, conventional substances soluble or dispersible in water,

(2) an oil phase which is composed essentially of constituents of low volatility and which comprises, if desired, conventional substances soluble or dispersible in the oil phase,

(3) one or more polyethoxylated O/W emulsifiers and/or one or more polypropoxylated O/W emulsifiers and/or one or more polyethoxylated and polypropoxylated O/W emulsifiers, and

(4) if desired, one or more W/O emulsifiers,

characterized in that

(a) the initial concentrations of the oil phase, the aqueous phase and, if desired, one or more W/O emulsifiers are chosen and these constituents are added to one another,

(b) the initial concentration of the O/W emulsifier or emulsifiers, which may also be equal to zero, is chosen and this O/W emulsifier or these O/W emulsifiers are added to the mixture obtained in

(a),

(c) the mixture obtained in (b) having a starting temperature,

(d) the mixture obtained in (b) by appropriate variation of at least one parameter selected from the group comprising the temperature and the concentration or concentrations of at least one of the chosen emulsifiers and/or of the oil phase and/or of the aqueous phase, and the mixture formed passes through the phase inversion region between W/O emulsions and O/W emulsions and is brought into the region where the mixture exists as an O/W emulsion or O/W microemulsion, and

(e) the mixture obtained in (d) is then optionally subjected to further processing steps,

is also regarded as an advantageous embodiment of the present invention.

Also advantageous according to the invention are processes in which the variation of the parameter or parameters consists in

(d1) varying the temperature of the mixture at a given concentration of the O/W emulsifier or emulsifiers and of the aqueous phase and the oil phase, or

(d2) varying the concentration of at least one O/W emulsifier at a given temperature, or

(d3) varying the concentration of the oil phase and/or the concentration of the aqueous phase at a given temperature and a given concentration of at least one O/W emulsifier.

It may be preferable according to the invention to vary several parameters simultaneously or successively.

Advantageous O/W microemulsions can be obtained according to the invention if the proportion of O/W emulsifier is below 20% by weight, especially below 15% by weight, based on the total weight of the preparation, and if less than 5% by weight of an additional W/O emulsifier is present.

It is possible in specific cases for the concentrations to be slightly above or below the abovementioned

limits and for the appropriate emulsion types nevertheless to be obtained. This comes as no surprise to those skilled in the art in view of the wide diversity of suitable emulsifiers and oil constituents, so they know that the scope of the present invention is not exceeded if the concentrations are above or below said limits.

Fig. 1 is a greatly simplified representation of a phase diagram. The variable parameter P is plotted against the temperature θ as the second variable. P here represents a concentration parameter, being either the proportion of the oil phase, the proportion of the aqueous phase or the concentration of an emulsifier or emulsifier mixture. For systems according to the invention it is the case that an O/W emulsion is present at lower temperatures and it is possible to pass through the phase inversion region when the temperature is raised. W/O emulsions are observed when the temperature is raised further. The structure of the system in the phase inversion region does not appear to be critical for the present invention. It is conceivable, for example, that lamellar phases, bicontinuous phases or cubic, hexagonal or inverse hexagonal phases are present in the phase inversion region and also that the phase inversion region is composed of several identical or more or less different phases.

The phase inversion region can be represented mathematically as a set of points within the linear system of coordinates Σ, which is formed by the variables of temperature, concentration of a suitable emulsifier or an emulsifier mixture in the preparation, and respective concentrations of the oil phase and aqueous phase, according to the following expression:

$$\Sigma = \{O, \theta, m, H, W\}$$

where O = origin of coordinates

θ = temperature

m = concentration of the emulsifier/ emulsifier mixture

H = concentration of the oil phase

W = concentration of the aqueous phase

Strictly speaking, in a multicomponent emulsifier system, it is of course necessary to take into account the contribution m_i of each individual emulsifier to the total function, which leads to the following expression in the case of an i-component emulsifier system:

$$\Sigma = \{O, \theta, m_1, m_2, \ldots, m_i, H, W\}.$$

In the mathematical sense, the phase inversion region Φ is a coherent area or a large number of coherent areas within the system of coordinates Σ. Φ represents the total number of coordinate points $K(\theta, a, m_1, m_2, \ldots, m_i, H, W)$ which determine mixtures according to the invention of aqueous phase of concentration W, oil phase of concentration H, and i emulsifiers according to the invention of concentration m_i at temperature θ, and for which phase inversion occurs when passing from a coordinate $K_1 \notin \Phi$ to a coordinate $K_2 \in \Phi$, as described in Fig. 2.

It is irrelevant whether the phase inversion region of a given system is a single coherent (i + 3)-dimensional area or consists of several such areas which are coherent but separated from one another, i.e. corresponds to several phase inversion regions of a given system. The present disclosure will therefore always refer, by way of generalization, to "the" or "a" phase inversion region, even if there are two or more such regions separated from one another.

The variable coordinates indicated in Fig. 2 are the temperature θ and the concentration parameter P described above, although which particular concentration parameter is involved can be left unspecified. In the transition from K_1 to K_2, only the temperature is raised and the other variables are kept constant.

This process is not reversible under the conditions according to the invention, i.e. if the system returns from the coordinate $K_2 \in \Phi$ to the coordinate $K_1 \notin \Phi$, transparent O/W microemulsions according to the invention can be obtained.

Accordingly a microemulsion according to the

invention is advantageously prepared in practice by a process in which, after choosing suitable raw materials, i.e. aqueous and oil phases, one or more O/W emulsifiers used according to the invention, the latter being present in concentrations at which phase inversion is possible for the given mixture, and optionally other substances, the individual components are added to one another, with stirring, phase inversion is induced by raising the temperature of the mixture, and the mixture is then left to cool to room temperature, with constant stirring.

It is also possible, however, to vary several parameters simultaneously, as indicated in Fig. 3. Fig. 3 shows a plot of the concentration of the aqueous phase against the temperature. Starting from the coordinate $K_1 \notin \Phi$, it is possible to reach the coordinates $K_2 \notin \Phi$ and $K_4 \notin \Phi$ or $K_3 \in \Phi$ by raising the temperature while keeping all the other parameters constant. Starting from the coordinates K_3 and K_4, it is possible to obtain O/W microemulsions according to the invention by lowering the temperature back to the coordinate K_1 while keeping all the other parameters constant.

Starting from the coordinates K_3 and K_4, it is possible to reach the coordinate K_5 and obtain O/W microemulsions according to the invention by lowering the temperature and additionally varying the concentration of the oil phase (in Fig. 3 by the addition of water).

It follows from Fig. 3 that, although the coordinate K_4 is outside the phase inversion region, it is possible to obtain systems starting from K_4 which are similar to those obtained starting from K_3, simply because the phase inversion region also has to be crossed when the temperature is lowered starting from K_4.

Again, starting from the coordinate K_1, it is possible to reach the coordinate K_5 and to obtain O/W microemulsions according to the invention by varying the concentration of the aqueous phase, i.e. by the addition of water, for example, as shown in Fig. 3. It must be said, however, that in this case there must already be an O/W microemulsion according to the invention in the form

of a concentrate, as it were, which is then converted by dilution to an O/W microemulsion according to the invention of different composition.

It was after all surprising, however, and therefore constitutes an original inventive step, that starting from the coordinate K_2, which lies outside the phase inversion region, O/W microemulsions according to the invention are also obtainable, without passing through phase inversion, simply by varying the temperature back to the coordinate K_1 or by additionally varying the concentration of the oil phase, i.e. by addition dilution with an aqueous phase, for example, to the coordinate K_5. This is advantageously done by a process in which a mixture of the base components, comprising the aqueous phase, the oil phase, one or more of the O/W emulsifiers used according to the invention, one or more W/O emulsifiers, if desired, and other auxiliary substances, additives and/or active substances which form an O/W emulsion below the phase inversion temperature range, if desired, is brought to a temperature

- at which the components soluble in the oil phase are either dissolved or at least in the molten state,
- which corresponds at least to the melting point of the highest-melting oil component not present in the dissolved state,
- and which is below the phase inversion temperature range of the system,

and the resulting O/W emulsion is then cooled to room temperature to form an O/W microemulsion. This is preferably carried out with stirring.

This process according to the invention is particularly suitable when heat-sensitive or highly volatile substances are to be incorporated into the O/W microemulsions according to the invention. Furthermore, this process, which is to be carried out at relatively low temperatures, is energy-saving compared with conventional processes.

Fig. 4 describes the case in which there is initially no O/W emulsifier according to the invention at

the coordinate L_1 and in which the system is brought to a coordinate $L_3 \notin \Phi$ or to a coordinate $L_2 \notin \Phi$ by raising the temperature. The coordinate L_2 can of course also be reached by cooling a system present at the coordinate L_3. The coordinates L_2 and L_3, at which W/O emulsions can be present, for example, basically differ only in that the temperature corresponding to L_3 is higher than any temperature which can correspond to the phase inversion temperature range.

The presence of an additional W/O emulsifier in systems symbolized in Fig. 4 is not absolutely necessary, albeit advantageous. The addition of an O/W emulsifier according to the invention or several such emulsifiers at the coordinates L_2 or L_3, while lowering the temperature, moves the system towards the coordinate L_4, which then corresponds to an O/W microemulsion according to the invention.

Another advantageous embodiment of the process according to the invention accordingly consists of a process in which, after choosing suitable raw materials, i.e. the water and oil phases and optionally other substances, the individual components are brought, with stirring, to a temperature at which phase inversion is possible for the given mixture, phase inversion is induced by addition to the mixture of the O/W emulsifier or emulsifiers used according to the invention, and the mixture is then left to cool to room temperature, with constant stirring.

It is within the capability of those skilled in the art to determine by means of simple experiments the appropriate temperature range within which a given mixture can undergo phase inversion. This temperature range should conventionally be chosen between 70 and 95°C, but can also be situated above or below these values in specific cases.

In practice, in the preparation of a microemulsion according to the invention, it is also possible and perhaps even advantageous to exceed the temperature range which can correspond to the phase inversion region,

because this region then has to be crossed on cooling to room temperature.

The effect of adding electrolytes is to change the solubility properties of a hydrophilic emulsifier. The microemulsions according to the invention therefore advantageously contain electrolytes, especially one or more salts with the following anions: chlorides and also inorganic oxo anions, including especially sulphates, carbonates, phosphates, borates and aluminates. Electrolytes based on organic anions can also advantageously be used, examples being lactates, acetates, benzoates, propionates, tartrates, citrates, etc. Comparable effects can also be achieved by ethylenediaminetetraacetic acid and its salts.

Ammonium, alkylammonium, alkali metal, alkaline earth metal, magnesium, iron or zinc ions are preferably used as the cations of the salts. It is self-evident that only biocompatible electrolytes should be used in cosmetics. On the other hand, at least in principle, special medicinal applications of the microemulsions according to the invention can require the use of electrolytes which should not be used without medical supervision.

Potassium chloride, sodium chloride, magnesium sulphate, zinc sulphate and mixtures thereof are particularly preferred. Salt mixtures such as those occurring in the natural salt from the Dead Sea are also advantageous.

The concentration of the electrolyte or electrolytes should be about 0.1 - 10.0% by weight, particularly advantageously about 0.3 - 8.0% by weight, based on the total weight of the preparation.

If the microemulsions according to the invention represent bases for cosmetic deodorants/antiperspirants, all the popular active substances can advantageously be used, for example odour masking substances such as the popular perfume constituents, odour absorbers, for example the sheet silicates described in German Offenlegungsschrift DE-P 40 09 347, including especially

montmorillonite, kaolinite, ilite, beidellite, nontronite, saponite, hectorite, bentonite and smectite, and also, for example, zinc salts of ricinoleic acid. It is also appropriate to incorporate antibacterial agents into the microemulsions according to the invention. Examples of advantageous substances are 2,4,4'-trichloro-2'-hydroxydiphenyl ether (irgasan), 1,6-di(4-chlorophenylbiguanido)hexane (chlorhexidine), 3,4,4'-trichlorocarbanilide, quaternary ammonium compounds, oil of cloves, oil of mint, oil of thyme, triethyl citrate, farnesol (3,7,11-trimethyl-2,6,10-dodecatrien-1-ol) and the active agents described in German Offenlegungsschriften DE-37 40 186, DE-39 38 140, DE-42 04 321, DE-42 29 707, DE-42 29 737, DE-42 37 081, DE-43 09 372 and DE-43 24 219.

The conventional antiperspirant substances can also advantageously be used in the microemulsions according to the invention, especially astringents, for example basic aluminium chlorides.

The cosmetic deodorants according to the invention can be in the form of aerosols, i.e. preparations sprayable from aerosol containers or squeeze bottles or by means of a pumping device, or in the form of liquid compositions applicable by means of roll-on devices, or else in the form of microemulsions applicable from normal bottles and containers.

Suitable propellants for cosmetic deodorants according to the invention, sprayable from aerosol containers, are the conventional, known, highly volatile, liquefied propellants, for example hydrocarbons (propane, butane, isobutane), which can be used on their own or in a mixture with one another. It is also advantageous to use compressed air.

Those skilled in the art are naturally aware that there are inherently non-toxic propellant gases which in principle would be suitable for the present invention, but which should nevertheless not be used because of a harmful effect on the environment or other concomitant circumstances, said propellant gases being

chlorofluorocarbons (CFCs) in particular.

It has also been found, surprisingly, that when using propellants soluble in the oil phase, i.e. conventional propane/butane mixtures, for example, the O/W microemulsions according to the invention are not simply sprayed as aerosol droplets but develop into small-cell concentrated foams as soon as said systems laden with said propellants undergo depressurization.

Such after-foaming preparations are therefore also regarded as advantageous embodiments of the present invention, with an original inventive step.

When propellants insoluble in the oil phase are used, the O/W microemulsions according to the invention are sprayed as aerosol droplets.

Other advantageous cosmetic and dermatological preparations are those which are in the form of a sunscreen. In addition to the active substance combinations according to the invention, these preferably contain at least one UVA filter and/or at least one UVB filter and/or at least one inorganic pigment.

However, it is also advantageous in terms of the present invention to produce cosmetic and dermatological preparations whose main purpose is not to protect from sunlight, but which nevertheless contain substances for UV protection. Thus UVA and/or UVB filters are usually incorporated e.g. into day creams.

Preparations according to the invention can advantageously contain substances which absorb UV radiation in the UVB region, the total amount of filters being e.g. 0.1% by weight to 30% by weight, preferably 0.5 to 10% by weight and especially 1 to 6% by weight, based on the total weight of the preparations.

The UVB filters can be oil-soluble or water-soluble. The following may be mentioned as examples of oil-soluble substances:

- 3-benzylidenecamphor and its derivatives, e.g. 3-(4-methylbenzylidene)camphor;
- 4-aminobenzoic acid derivatives, preferably 2-ethylhexyl 4-(dimethylamino)benzoate, amyl 4-(dimethyl-

amino)benzoate;

- cinnamic acid esters, preferably 2-ethylhexyl 4-methoxycinnamate, isopentyl 4-methoxycinnamate;
- salicylic acid esters, preferably 2-ethylhexyl salicylate, 4-isopropylbenzyl salicylate, homomenthyl salicylate;
- benzophenone derivatives, preferably 2-hydroxy-4-methoxybenzophenone, 2-hydroxy-4-methoxy-4'-methylbenzophenone, 2,2'-dihydroxy-4-methoxybenzophenone;
- benzalmalonic acid esters, preferably di(2-ethylhexyl) 4-methoxybenzalmalonate;
- 2,4,6-trianilino(p-carbo-2'-ethyl-1'-hexyloxy)-1,3,5-triazine.

The following are advantageous as water-soluble substances:

- 2-phenylbenzimidazole-5-sulphonic acid and its salts, e.g. the sodium, potassium or triethanolammonium salts;
- sulphonic acid derivatives of benzophenones, preferably 2-hydroxy-4-methoxybenzophenone-5-sulphonic acid and its salts;
- sulphonic acid derivatives of 3-benzylidenecamphor, e.g. 4-(2-oxo-3-bornylidenemethyl)benzenesulphonic acid, 2-methyl-5-(2-oxo-3-bornylidenemethyl)benzenesulphonic acid and their salts.

Of course, the list of said UVB filters which can be used according to the invention is not intended to imply a limitation.

The invention also provides the combination of a UVA filter according to the invention with a UVB filter or a cosmetic or dermatological preparation according to the invention which also contains a UVB filter.

UVA filters which have hitherto conventionally been present in cosmetic and/or dermatological preparations can also advantageously be used in preparations according to the invention. These substances are preferably dibenzoylmethane derivatives, especially 1-(4'-tert-butylphenyl)-3-(4'-methoxyphenyl)propane-1,3-dione and 1-phenyl-3-(4'-isopropylphenyl)propane-1,3-dione. The

invention also provides preparations containing these combinations. The amounts of UVA filters can be the same as those used for UVB filters.

Cosmetic and/or dermatological preparations according to the invention can also contain inorganic pigments which are conventionally used in cosmetics for protecting the skin from UV rays. Said inorganic pigments are oxides of titanium, zinc, iron, zirconium, silicon, manganese, aluminium and cerium and mixtures thereof, as well as modifications in which the oxides are the active agents. Pigments based on titanium dioxide are particularly preferred. The amounts used can be those mentioned for the above combinations.

A surprising characteristic of the present invention is that preparations according to the invention are very good vehicles for carrying cosmetic or dermatological active substances into the skin, advantageous active substances being antioxidants which can protect the skin from oxidative stress.

According to the invention the preparations advantageously contain one or more antioxidants. Favourable, albeit optional antioxidants which can be used are any antioxidants suitable or conventional for cosmetic and/or dermatological applications. It is advantageous here to use antioxidants as the only class of active substances, for instance when the principal application is cosmetic or dermatological, such as protecting the skin from oxidative stress. It is also favourable, however, to provide the microemulsions according to the invention with one or more antioxidants when the preparations are intended to serve a different purpose, e.g. as deodorants or sunscreens.

The antioxidants are particularly advantageously selected from the group comprising amino acids (e.g. histidine, tyrosine, tryptophan) and their derivatives, imidazoles (e.g. urocanic acid) and their derivatives, peptides such as D,L-carnosine, D-carnosine, L-carnosine and their derivatives (e.g. anserine), carotenoids, carotenes (e.g. α-carotene, β-carotene, lycopene) and

their derivatives, lipoic acid and its derivatives (e.g. dihydrolipoic acid), aurothioglucose, propylthiouracil and other thiols (e.g. thioredoxin, glutathione, cysteine, cystine, cystamine and their glycosyl, N-acetyl, methyl, ethyl, propyl, amyl, butyl, lauryl, palmitoyl, oleyl, gamma-linoleyl, cholesteryl and glyceryl esters) and their salts, dilauryl thiodipropionate, distearyl thiodipropionate, thiodipropionic acid and its derivatives (esters, ethers, peptides, lipids, nucleotides, nucleosides and salts) and sulphoximine compounds (e.g. buthionine sulphoximines, homocysteine sulphoximine, buthionine sulphones, penta-, hexa-, hepta-thionine sulphoximine) in very low tolerated doses (e.g. pmol to μmol/kg), and also (metal) chelating agents (e.g. α-hydroxy fatty acids, α-hydroxypalmitic acid, phytic acid, lactoferrin), α-hydroxy acids (e.g. citric acid, lactic acid, malic acid), humic acid, bile acid, bile extracts, bilirubin, biliverdin, EDTA, EGTA and its derivatives, unsaturated fatty acids and their derivatives (e.g. gamma-linolenic acid, linoleic acid, oleic acid), folic acid and its derivatives, ubiquinone and ubiquinol and their derivatives, vitamin C and derivatives (e.g. ascorbyl palmitates, Mg ascorbyl phosphates, ascorbyl acetates), tocopherols and derivatives (e.g. vitamin E acetate), vitamin A and derivatives (vitamin A palmitate), and coniferyl benzoate of benzoin, rutinic acid and its derivatives, ferulic acid and its derivatives, butylhydroxytoluene, butylhydroxyanisole, nordihydroguaiac acid, nordihydroguaiaretic acid, trihydroxybutyrophenone, uric acid and its derivatives, zinc and its derivatives (e.g. ZnO, $ZnSO_4$), selenium and its derivatives (e.g. selenomethionine), stilbenes and their derivatives (e.g. stilbene oxide, trans-stilbene oxide), and the derivatives (salts, esters, ethers, sugars, nucleotides, nucleosides, peptides and lipids) of said active substances which are suitable according to the invention.

It can be particularly advantageous in terms of the present invention to use oil-soluble antioxidants.

The amount of antioxidants (one or more compounds) in the preparations is preferably 0.001 to 30% by weight, particularly preferably 0.05 - 20% by weight and especially 1 - 10% by weight, based on the total weight of the preparation.

If the antioxidant or antioxidants are vitamin E and/or its derivatives, their respective concentrations are advantageously chosen within the range 0.001 - 10% by weight, based on the total weight of the formulation.

If the antioxidant or antioxidants are vitamin A or vitamin A derivatives or carotenes or their derivatives, their respective concentrations are advantageously chosen within the range 0.001 - 10% by weight, based on the total weight of the formulation.

Those skilled in the art are of course aware that high-quality cosmetic preparations cannot usually be conceived without the conventional auxiliary substances and additives. These include, for example, agents for providing consistency, fillers, perfume, dyestuffs, emulsifiers, additional active substances such as vitamins or proteins, light protection agents, stabilizers, insect repellents, alcohol, water, salts, substances with an antimicrobial, proteolytic or keratolytic action, etc.

If desired, the aqueous phase of the O/W micro-emulsions according to the invention can also contain thickeners so that the overall preparation has a gel-like appearance and can be thought of as a microemulsion gel. Carrageenan or PEG-4 rapeseed amides, and laureth-2 amide MEA, for example, have proved to be suitable thickeners.

According to the invention, active substances can also very advantageously be selected from the group comprising lipophilic active substances, and especially from the following group:

acetylsalicylic acid, atropine, azulene, hydrocortisone and its derivatives, e.g. hydrocortisone 17-valerate, vitamins, e.g. ascorbic acid and its derivatives, B and D vitamins and very favourably vitamin B_1, vitamin B_{12} and vitamin D_1, as well as bisabolol, unsaturated fatty

acids, particularly the essential fatty acids (also often called vitamin F), especially gamma-linolenic acid, oleic acid, eicosapentaenoic acid, docosahexaenoic acid and its derivatives, chloramphenicol, caffeine, prostaglandins, thymol, camphor, extracts or other products of vegetable and animal origin, e.g. evening primrose oil, borage oil or currant seed oil, fish oils, cod-liver oil and also ceramides and ceramide-like compounds, etc.

Although the use of hydrophilic active substances is of course also encouraged according to the invention, a further advantage of the microemulsions according to the invention is that the large number of very fine droplets are particularly effective at making oil-soluble or lipophilic active substances bioavailable.

It is also advantageous to select the active substances from the group comprising superfatting substances, for example purcellin oil, Eucerit® and Neocerit®.

It is also possible, and may be advantageous, to add washing-active surfactants to the preparations according to the invention. Aqueous cosmetic cleansers according to the invention, or low-water or water-free cleanser concentrates intended for aqueous cleansing, can contain cationic, anionic, non-ionic and/or amphoteric surfactants, for example conventional soaps, e.g. sodium salts of fatty acids, alkylsulphates, alkyl ether sulphates, alkanesulphonates, alkylbenzenesulphonates, sulphoacetates, sulphobetaines, sarcosinates, amidosulphobetaines, sulphosuccinates, sulphosuccinic acid half-esters, alkyl ether carboxylates, protein/fatty acid condensates, alkylbetaines and amidobetaines, fatty acid alkanolamides and polyglycol ether derivatives.

Cosmetic preparations which constitute cosmetic skin cleansing preparations can be in liquid or semisolid form, for example in the form of gels. They preferably contain at least one anionic, cationic, non-ionic or amphoteric surface-active substance or mixtures thereof, and optionally electrolytes and auxiliary substances such

as those conventionally used for this purpose. The surface-active substance can preferably be present in the cleansing preparations in a concentration of between 1 and 30% by weight, based on the total weight of the preparations.

Cosmetic preparations which constitute a shampoo preferably contain at least one anionic, non-ionic or amphoteric surface-active substance or mixtures thereof, and optionally electrolytes and auxiliary substances such as those conventionally used for this purpose. The surface-active substance can preferably be present in the cleansing preparations in a concentration of between 1 and 50% by weight, based on the total weight of the preparations. Cetyltrimethylammonium salts, for example, are advantageously used.

Apart from the abovementioned surfactants, the preparations according to the invention for cleansing the hair or skin contain water and optionally the additives conventionally used in cosmetics, for example perfume, thickeners, dyestuffs, deodorants, antimicrobial substances, superfatting agents, complexing and sequestering agents, pearlescent agents, plant extracts, vitamins, active substances and the like.

Despite their oil content, the preparations according to the invention surprisingly have a very good foaming capacity and a high cleansing power and have a substantial regenerating action on the general condition of the skin. In particular, the preparations according to the invention have a skin smoothing action, reduce the dry feel of the skin and make the skin supple.

If the microemulsions according to the invention are to be used for hair care, they can contain the conventional constituents, normally e.g. film-forming polymers. Of said polymers with at least partially quaternized nitrogen groups (called "film-forming agents" hereafter), those which are preferentially suitable are selected from the group of substances carrying the name "polyquaternium" according to INCI nomenclature (International Nomenclature Cosmetic Ingredient), for

example:

polyquaternium-2	(Chemical Abstracts no. 63451-27-4, e.g. Mirapol® A-15)
polyquaternium-5	(copolymer of acrylamide and β-methacryloxyethyltrimethylammonium methosulphate, CAS no. 26006-22-4)
polyquaternium-6	(homopolymer of N,N-dimethyl-N-2-propenyl-2-propen-1-aminium chloride, CAS no. 26062-79-3, e.g. Merquat® 100)
polyquaternium-7	N,N-dimethyl-N-2-propenyl-2-propen-1-aminium chloride, polymer with 2-propenamide, CAS no. 26590-05-6, e.g. Merquat® S
polyquaternium-10	quaternary ammonium salt of hydroxyethyl cellulose, CAS no. 53568-66-4, 55353-19-0, 54351-50-7, 68610-92-4, 81859-24-7, e.g. Celquat® SC-230M
polyquaternium-11	vinylpyrrolidone/dimethylaminoethyl methacrylate copolymer/diethyl sulphate reaction product, CAS no. 53633-54-8, e.g. Gafquat® 755N
polyquaternium-16	vinylpyrrolidone/vinylimidazolinium methochloride copolymer, CAS no. 29297-55-0, e.g. Luviquat® HM 552
polyquaternium-17	CAS no. 90624-75-2, e.g. Mirapol® AD-1
polyquaternium-19	quaternized water-soluble polyvinyl alcohol
polyquaternium-20	water-dispersible quaternized polyvinyl octadecyl ether
polyquaternium-21	polysiloxane/polydimethyldimethylammonium acetate copolymer, e.g. Abil® B 9905
polyquaternium-22	dimethyldiallylammonium chloride/acrylic acid copolymer, CAS no. 53694-7-0, e.g. Merquat® 280
polyquaternium-24	polymeric quaternary ammonium salt of hydroxyethyl cellulose, reaction product with an epoxide substituted by lauryldimethylammonium, CAS no.

	107987-23-5, e.g. Quatrisoft® LM-200
polyquaternium-28	vinylpyrrolidone/methacrylamido-propyltrimethylammonium chloride co-polymer, e.g. Gafquat® HS-100
polyquaternium-29	e.g. Lexquat® CH
polyquaternium-31	CAS no. 136505-02-7, e.g. Hypan® QT 100
polyquaternium-32	N,N,N-trimethyl-2-[(2-methyl-1-oxo-2-propenyl)oxy]ethanaminium chloride, polymer with 2-propenamide, CAS no. 35429-19-7
polyquaternium-37	CAS no. 26161-33-1

Hair care preparations according to the invention advantageously contain 0.01 - 5% by weight of one or more film-forming agents, preferably 0.1 - 3% by weight and especially 0.2 - 2% by weight, based in each case on the total weight of the preparations. These embodiments of the preparations according to the invention treat hair damaged or stressed by environmental influences or protect it from such environmental influences. Furthermore, the preparations according to the invention impart a looser body and strength to the hair style without having a sticky effect.

Accordingly, depending on their composition, the preparations according to the invention can be used for example as a skin protection emulsion, cleansing milk, sunscreen lotion, nutrient lotion, day or night emulsion, etc.

The microemulsions according to the invention also make an outstanding contribution to skin smoothness, especially when they include one or more substances which promote skin smoothness.

It may be possible and advantageous to use the preparations according to the invention as a base for pharmaceutical formulations. Appropriate requirements apply, mutatis mutandis, to the formulation of medicinal preparations. The boundaries between pure cosmetics and pure pharmaceuticals are fluid here. According to the invention, suitable pharmaceutical active substances are

basically all classes of active substances, lipophilic active substances being preferred. Examples are antihistamines, antiphlogistics, antibiotics, antimycotics, active substances for stimulating the circulation, keratolytics, hormones, steroids, vitamins, etc.

The cosmetic and dermatological preparations according to the invention can contain cosmetic auxiliary substances such as those conventionally used in such preparations, e.g. preservatives, bactericides, virucides, perfumes, antifoams, dyestuffs, pigments with a colouring effect, thickeners, surface-active substances, emulsifiers, plasticizing, moisturizing and/or moisture-retaining substances, anti-inflammatories, drugs, fats, oils, waxes or other conventional constituents of a cosmetic or dermatological formulation, such as alcohols, polyols, polymers, foam stabilizers, electrolytes or organic solvents.

It is particularly advantageous to use mixtures of the abovementioned solvents.

Other constituents which can be used are fats, waxes and other natural and synthetic fatty substances, preferably esters of fatty acids with alcohols having a small number of C atoms, e.g. with isopropanol, propylene glycol or glycerol, or esters of fatty alcohols with alkanoic acids having a small number of C atoms or with fatty acids, alcohols, diols or polyols having a small number of C atoms, and their ethers, preferably ethanol, isopropanol, propylene glycol, glycerol, ethylene glycol, ethylene glycol monoethyl or monobutyl ether, propylene glycol monomethyl, monoethyl or monobutyl ether, diethylene glycol monomethyl or monoethyl ether, and analogous products.

The following Examples will illustrate the present invention.

Example 1

Deodorant preparation

	% by weight
Glyceryl isostearate	1.800
PEG-15 cetylstearyl alcohol	5.100
Octyl isostearate	3.300
Cyclomethicone	6.600
Sorbitol	2.900
Glycerol monocaprate	0.100
Aluminium chlorhydrate	3.900
Perfume, antioxidants	q.s.
Water	ad 100.000

The oil phase and the aqueous phase are each heated separately to 85 - 90°C, combined and cooled to room temperature with phase inversion to form a transparent O/W microemulsion.

Example 2

Deodorant preparation

	% by weight
Glyceryl isostearate	1.800
PEG-15 cetylstearyl alcohol	5.200
Sorbitol	2.900
Isotridecyl isononanoate	3.300
Cyclomethicone	6.600
Glycerol monocaprate	0.100
Aluminium chlorhydrate	3.883
Perfume, antioxidants	q.s.
Water	ad 100.000

The oil phase and the aqueous phase are each heated separately to 85 - 90°C, combined and cooled to room temperature with phase inversion to form a transparent O/W microemulsion.

Example 3

Deodorant preparation

	% by weight
Glyceryl isostearate	1.800
PEG-17 cetylstearyl alcohol	5.200
Isotridecyl isononanoate	10.000
Sorbitol	2.900
Glycerol monocaprate	0.100
Aluminium chlorhydrate	3.900
Perfume, antioxidants	q.s.
Water	ad 100.000

The oil phase and the aqueous phase are each heated separately to 85 - 90°C, combined and cooled to room temperature with phase inversion to form a transparent O/W microemulsion.

Example 4

Deodorant preparation

	% by weight
Sorbitan monoisostearate	2.300
PEG-15 cetylstearyl alcohol	4.600
Sorbitol	2.900
Cyclomethicone	6.600
Isotridecyl isononanoate	3.300
Glycerol monocaprate	0.100
Aluminium chlorhydrate	3.900
Perfume, antioxidants	q.s.
Water	ad 100.000

The oil phase and the aqueous phase are each heated separately to 85 - 90°C, combined and cooled to room temperature with phase inversion to form a transparent O/W microemulsion.

Example 5

Deodorant preparation

	% by weight
Diglyceryl monoisostearate	1.800
PEG-15 cetylstearyl alcohol	5.100
C_{12-15}-Alkyl benzoate	5.000
Octyl isostearate	5.000
Sorbitol	2.900
Glycerol monocaprate	0.100
Aluminium chlorhydrate	3.900
Perfume, antioxidants	q.s.
Water	ad 100.000

The oil phase and the aqueous phase are each heated separately to 85 - 90°C, combined and cooled to room temperature with phase inversion to form a transparent O/W microemulsion.

Example 6

Deodorant preparation

	% by weight
Diglyceryl monoisostearate	2.300
PEG-15 cetylstearyl alcohol	4.600
Cyclomethicone	6.600
Sorbitol	2.900
Isotridecyl isononanoate	3.300
Glycerol monocaprate	0.100
Aluminium chlorhydrate	3.900
Perfume, antioxidants	q.s.
Water	ad 100.000

The oil phase and the aqueous phase are each heated separately to 85 - 90°C, combined and cooled to room temperature with phase inversion to form a transparent O/W microemulsion.

Example 7

Deodorant preparation

	% by weight
Glyceryl isostearate	1.800
PEG-16 stearyl alcohol	5.100
Octyl isostearate	3.300
Cyclomethicone	6.600
Sorbitol	2.900
Glycerol monocaprate	0.100
Aluminium chlorhydrate	3.900
Perfume, antioxidants	q.s.
Water	ad 100.000

The oil phase and the aqueous phase are each heated separately to 85 - 90°C, combined and cooled to room temperature with phase inversion to form a transparent O/W microemulsion.

Example 8

Deodorant preparation

	% by weight
Propylene glycol monoisostearate	2.300
PEG-15 cetylstearyl alcohol	4.600
Isotridecyl isononanoate	3.300
Cyclomethicone	6.600
Sorbitol	2.900
Glycerol monocaprate	0.100
Aluminium chlorhydrate	3.900
Perfume, antioxidants	q.s.
Water	ad 100.000

The oil phase and the aqueous phase are each heated separately to 85 - 90°C, combined and cooled to room temperature with phase inversion to form a transparent O/W microemulsion.

Example 9

Light protection preparation

	% by weight
Glyceryl isostearate	2.400
Isoceteth-20	4.800
Cetearyl isononanoate	1.670
Eusolex® 232	3.000
Cyclomethicone	3.330
NaOH	0.990
Glycerol	3.000
Perfume, preservatives, dyestuffs	q.s.
Water	ad 100.000

The oil phase and the aqueous phase are each heated separately to 85 - 90°C, combined and cooled to room temperature with phase inversion to form a transparent O/W microemulsion.

Example 10

Skin care emulsion

	% by weight
Glyceryl isostearate	2.400
PEG-60 evening primrose glycerides	4.800
Isotridecyl isononanoate	3.340
Cyclomethicone	6.660
Butylene glycol	3.000
Glycerol monocaprate	0.100
Perfume, preservatives, dyestuffs	q.s.
Water	ad 100.000

The oil phase and the aqueous phase are each heated separately to 85 - 90°C, combined and cooled to room temperature with phase inversion to form a transparent O/W microemulsion.

Example 11

Face cleansing emulsion

	% by weight
Glyceryl isolaurate	4.588
Laureth-11 carboxylic acid (90%)	3.754
Cetearyl isononanoate	1.773
Cyclomethicone	3.441
Butylene glycol	3.128
NaOH	0.206
Perfume, preservatives, dyestuffs	q.s.
Water	ad 100.000

The oil phase and the aqueous phase are each heated separately to 85 - 90°C, combined and cooled to room temperature with phase inversion to form a transparent O/W microemulsion.

Example 12

Body care lotion

	% by weight
PEG-20 stearate	4.800
Glyceryl isostearate	2.400
Isotridecyl isononanoate	6.660
Glycerol monocaprate	0.100
Cyclomethicone	3.340
Butylene glycol	3.000
Farnesol	0.300
Perfume, preservatives, dyestuffs	q.s.
Water	ad 100.000

The oil phase and the aqueous phase are each heated separately to 85 - 90°C, combined and cooled to room temperature with phase inversion to form a transparent O/W microemulsion.

Example 13

Aftershave emulsion

	% by weight
Sorbitan isostearate	2.400
Isotridecyl isononanoate	1.670
PEG-20 sorbitan monostearate	4.800
Butylene glycol	3.000
Glycerol monocaprate	0.100
Cyclomethicone	3.330
Farnesol	0.300
Perfume, preservatives, dyestuffs	q.s.
Water	ad 100.000

The oil phase and the aqueous phase are each heated separately to 85 - 90°C, combined and cooled to room temperature with phase inversion to form a transparent O/W microemulsion.

Example 14

Cleansing emulsion for greasy skin

	% by weight
Isotridecyl isononanoate	1.670
PEG-20 sorbitan monooleate	4.800
Cyclomethicone	3.330
Butylene glycol	3.000
Glycerol monooleate	2.400
Farnesol	0.300
Glycerol monocaprate	0.100
Perfume, preservatives, dyestuffs	q.s.
Water	ad 100.000

The oil phase and the aqueous phase are each heated separately to 85 - 90°C, combined and cooled to room temperature with phase inversion to form a transparent O/W microemulsion.

Example 15

Refreshing aftershave lotion

	% by weight
Isotridecyl isononanoate	3.311
Glyceryl isostearate	1.786
Oleth-15	5.146
Sorbitol	2.913
Glycerol monocaprate	0.194
Cyclomethicone	6.621
Farnesol	0.097
Ethanol	3.883
Perfume, preservatives, dyestuffs	q.s.
Water	ad 100.000

The oil phase and the aqueous phase are each heated separately to 85 - 90°C, combined and cooled to room temperature with phase inversion to form a transparent O/W microemulsion.

Example 16

Hair lotion

	% by weight
Glyceryl isostearate	2.400
Ceteareth-15	4.800
Caprylic/capric triglycerides	3.340
Butylene glycol	3.000
Glycerol monocaprate	0.100
Cyclomethicone	6.660
Farnesol	0.300
Perfume, preservatives, dyestuffs	q.s.
Water	ad 100.000

The oil phase and the aqueous phase are each heated separately to 85 - 90°C, combined and cooled to room temperature with phase inversion to form a transparent O/W microemulsion.

Example 17

Face care emulsion

	% by weight
Glyceryl isostearate	2.400
PEG-15 cetylstearyl alcohol	4.800
Dicaprylyl ether	5.000
Butylene glycol	3.000
Glycerol monocaprate	0.100
Farnesol	0.300
Perfume, preservatives, dyestuffs	q.s.
Water	ad 100.000

The oil phase and the aqueous phase are each heated separately to 85 - 90°C, combined and cooled to room temperature with phase inversion to form a transparent O/W microemulsion.

Example 18

Make-up remover lotion

	% by weight
Diglycerol monoisostearate	1.840
Ceteareth-15	5.300
Liquid paraffin	5.000
Sorbitol	3.000
Perfume, preservatives, dyestuffs	q.s.
Water	ad 100.000

The oil phase and the aqueous phase are each heated separately to 85 - 90°C, combined and cooled to room temperature with phase inversion to form a transparent O/W microemulsion.

Example 19

Deodorant emulsion

	% by weight
Ceteareth-15	5.146
Octyldodecanol	9.932
Sorbitol	2.913
Farnesol	0.097
Diglycerol monoisostearate	1.786
Glycerol monocaprate	0.194
Perfume, preservatives, dyestuffs	q.s.
Water	ad 100.000

The oil phase and the aqueous phase are each heated separately to 85 - 90°C, combined and cooled to room temperature with phase inversion to form a transparent O/W microemulsion.

Example 20

Face care lotion

	% by weight
PEG-6 caprylic/capric glycerides	4.800
Isotridecyl isononanoate	1.670
Butylene glycol	3.000
Glycerol monocaprate	2.400
Cyclomethicone	3.330
Perfume, preservatives, dyestuffs	q.s.
Water	ad 100.000

The oil phase and the aqueous phase are each heated separately to 85 - 90°C, combined and cooled to room temperature with phase inversion to form a transparent O/W microemulsion.

Example 21

	% by weight
Glyceryl isostearate	2.400
Isotridecyl isononanoate	1.670

Cyclomethicone	3.330
Butylene glycol	3.000
PEG-20 glyceryl isostearate	4.800
Farnesol	0.300
Glycerol monocaprate	0.100
Perfume, preservatives, dyestuffs	q.s.
Water	ad 100.000

The oil phase and the aqueous phase are each heated separately to 85 - 90°C, combined and cooled to room temperature with phase inversion to form a transparent O/W microemulsion.

Example 22

Cleansing preparation

	% by weight
Glyceryl isolaurate	4.600
Sodium laureth-1-4 sulphate (25%)	15.000
Cyclomethicone	3.440
Cetearyl isononanoate	1.770
Butylene glycol	3.125
Perfume, preservatives, dyestuffs	q.s.
Water	ad 100.000

The oil phase and the aqueous phase are each heated separately to 85 - 90°C, combined and cooled to room temperature with phase inversion to form a transparent O/W microemulsion.

Example 23

Microdispersion

	% by weight
Glyceryl isostearate	2.400
Ceteth-15	4.800
Cetyl palmitate	4.000
Butylene glycol	3.000
Perfume, preservatives, dyestuffs	q.s.

Water ad 100.000

The oil phase and the aqueous phase are each heated separately to 85 - 90°C, combined and cooled to room temperature with phase inversion to form a transparent O/W microemulsion.

Patent claims:

1. Transparent or translucent microemulsions of the oil-in-water type

- comprising an oil phase, composed essentially of constituents of low volatility, and an aqueous phase
- containing:
  one or more polyethoxylated O/W emulsifiers and/or one or more polypropoxylated O/W emulsifiers and/or one or more polyethoxylated and polypropoxylated O/W emulsifiers,
- and also containing one or more W/O emulsifiers, if desired,
- having an emulsifier content of less than 20% by weight, based on the total weight of the emulsion,
- and obtainable by a process in which a mixture of the base components, comprising the aqueous phase, the oil phase, one or more of the O/W emulsifiers according to the invention, one or more W/O emulsifiers, if desired, and other auxiliary substances, additives and/or active substances, if desired, is brought to a temperature within or above the phase inversion temperature range and then cooled to room temperature.

2. Process for the preparation of transparent or translucent O/W microemulsions which comprise:

(1) an aqueous phase comprising, if desired, conventional substances soluble or dispersible in water,

(2) an oil phase which is composed essentially of constituents of low volatility and which comprises, if desired, conventional substances soluble or dispersible in the oil phase,

(3) one or more polyethoxylated O/W emulsifiers and/or one or more polypropoxylated O/W emulsifiers and/or one or more polyethoxylated and polypropoxylated O/W emulsifiers, and

(4) if desired, one or more W/O emulsifiers,

characterized in that

(a) the initial concentrations of the oil phase, the

aqueous phase and, if desired, one or more W/O emulsifiers are chosen and these constituents are added to one another,

(b) the initial concentration of the O/W emulsifier or emulsifiers, which may also be equal to zero, is chosen and this O/W emulsifier or these O/W emulsifiers are added to the mixture obtained in (a),

(c) the mixture obtained in (b) having a starting temperature,

(d) the mixture obtained in (b) by appropriate variation of at least one parameter selected from the group comprising the temperature and the concentration or concentrations of at least one of the chosen emulsifiers and/or of the oil phase and/or of the aqueous phase, and the mixture formed passes through the phase inversion region between W/O emulsions and O/W emulsions and is brought into the region where the mixture exists as an O/W emulsion or O/W microemulsion, and

(e) the mixture obtained in (d) is then optionally subjected to further processing steps.

3. Process for the preparation of transparent or translucent O/W microemulsions according to Claim 1, characterized in that a mixture of the base components, comprising the aqueous phase, the oil phase, one or more of the O/W emulsifiers used according to the invention, one or more W/O emulsifiers, if desired, and other auxiliary substances, additives and/or active substances which form an O/W emulsion below the phase inversion temperature range, if desired, is brought to a temperature

- at which the components soluble in the oil phase are either dissolved or at least in the molten state,
- which corresponds at least to the melting point of the highest-melting oil component not present in the dissolved state,
- and which is below the phase inversion temperature range of the system,

and the resulting O/W emulsion is then cooled to room temperature to form an O/W microemulsion.

Abstract

Transparent or translucent microemulsions of the oil-in-water type

- comprising an oil phase, composed essentially of constituents of low volatility, and an aqueous phase
- containing:
  one or more polyethoxylated O/W emulsifiers and/or one or more polypropoxylated O/W emulsifiers and/or one or more polyethoxylated and polypropoxylated O/W emulsifiers,
- and also containing one or more W/O emulsifiers, if desired,
- having an emulsifier content of less than 20% by weight, based on the total weight of the emulsion,
- and obtainable by a process in which a mixture of the base components, comprising the aqueous phase, the oil phase, one or more of the O/W emulsifiers according to the invention, one or more W/O emulsifiers, if desired, and other auxiliary substances, additives and/or active substances, if desired, is brought to a temperature within or above the phase inversion temperature range and then cooled to room temperature.

Fig. 1

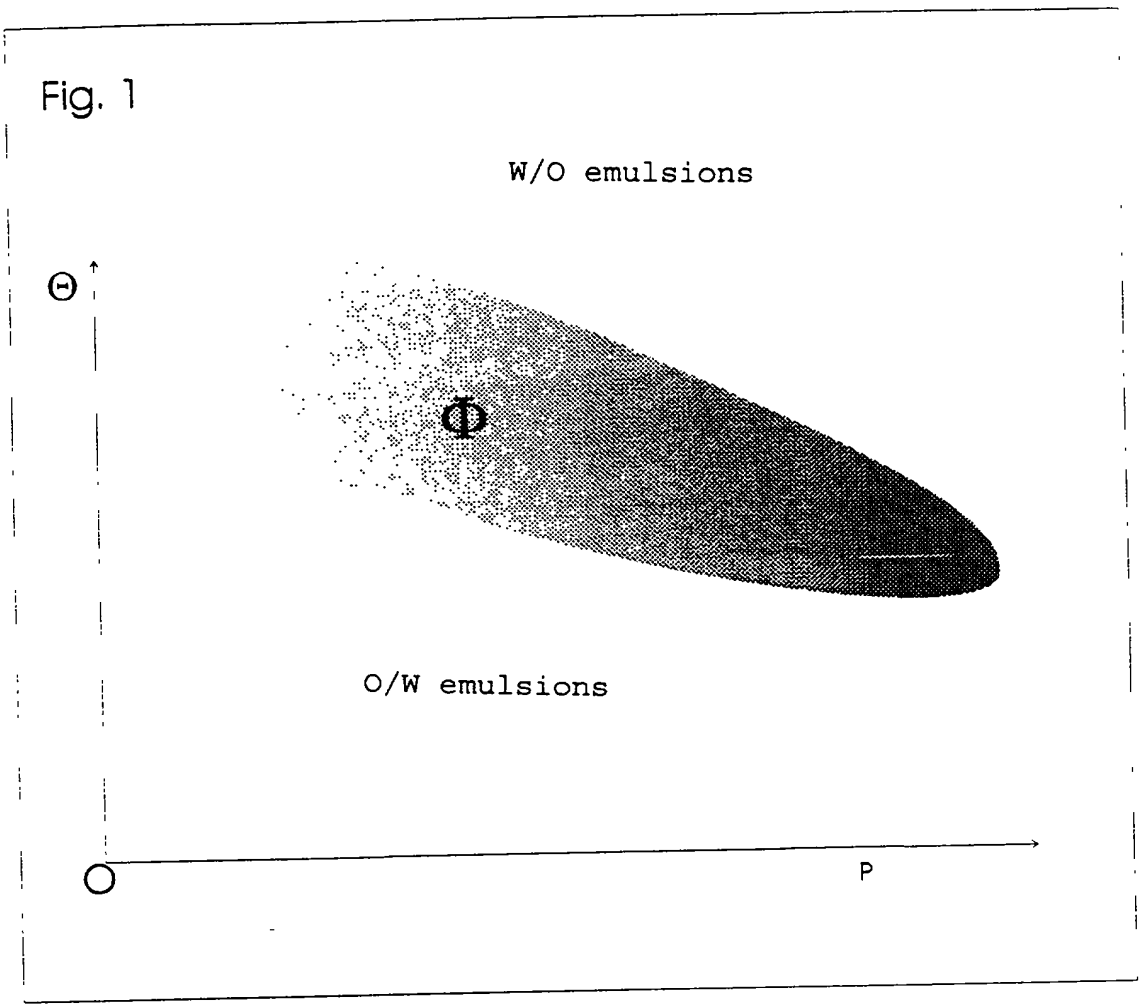


Fig. 2

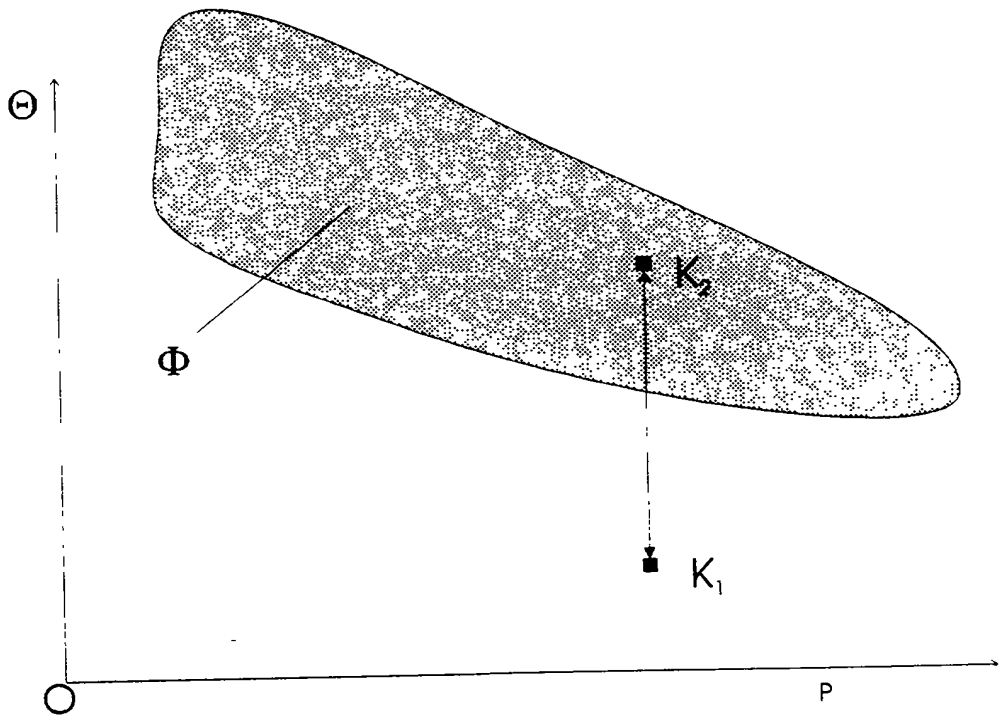


Fig. 3

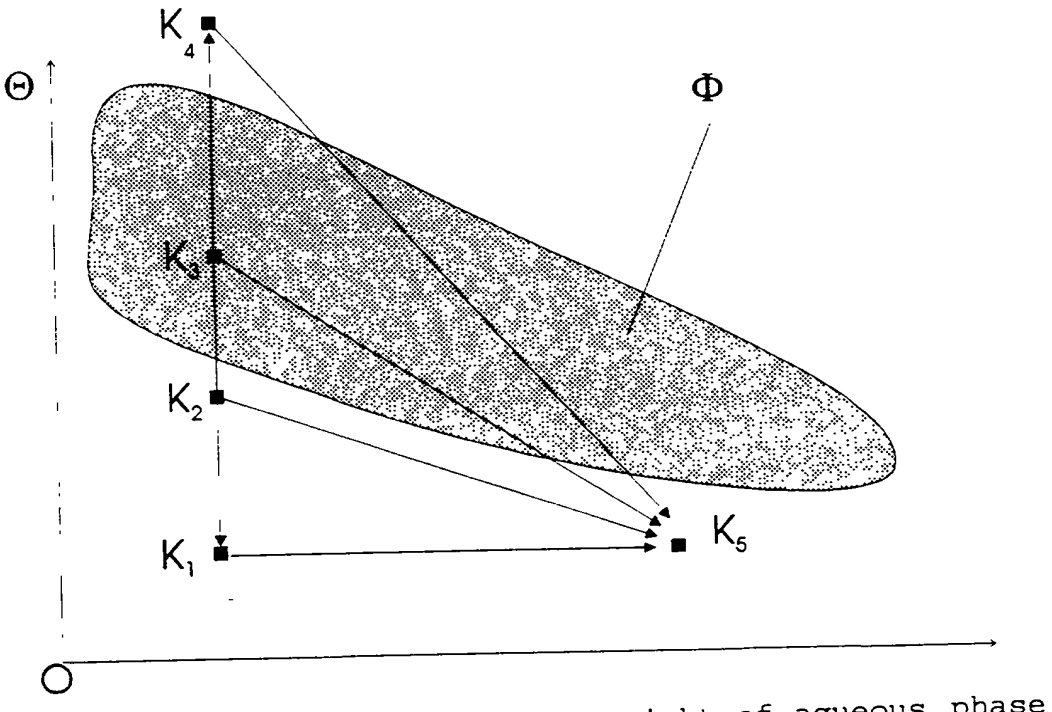
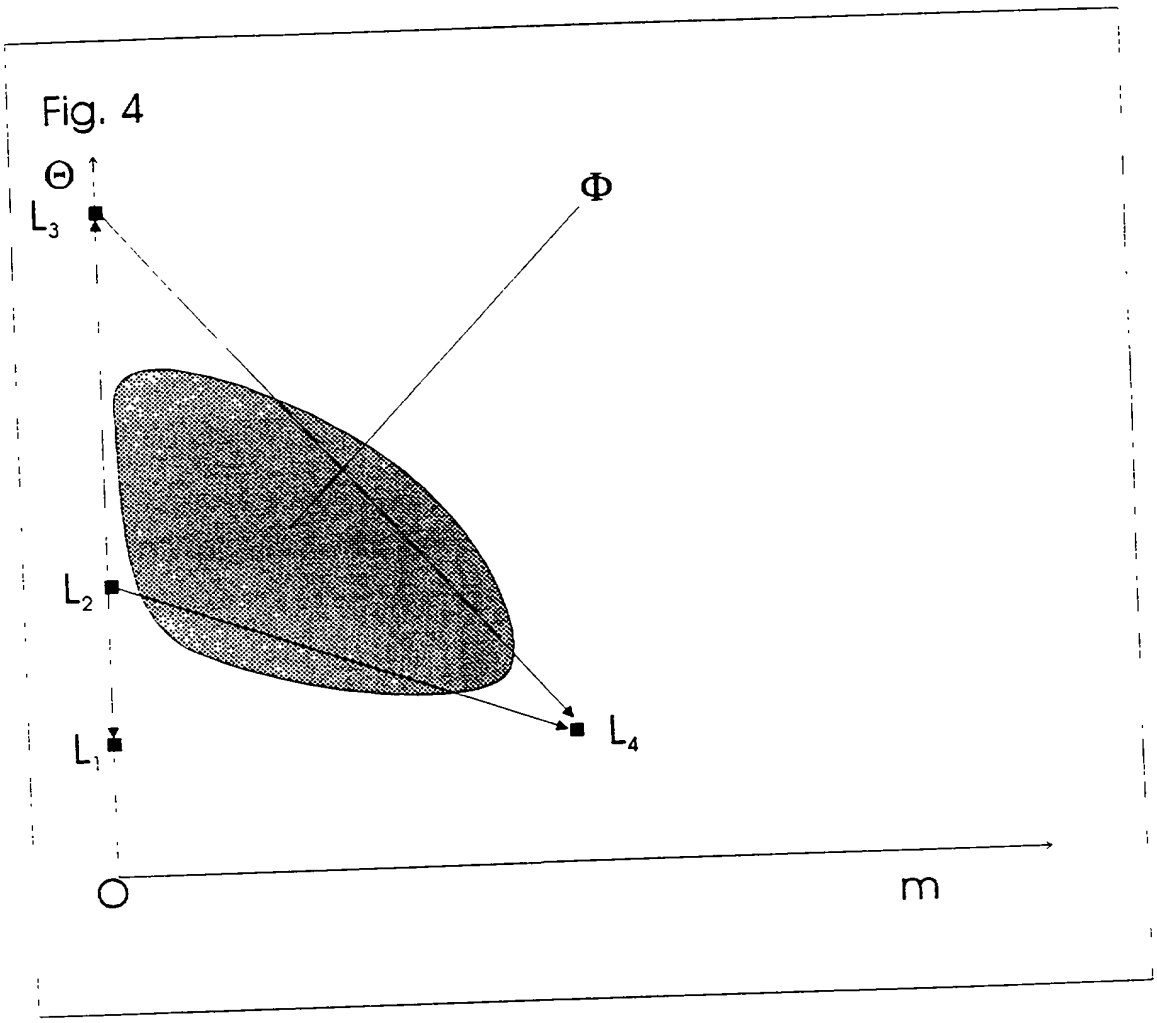


Fig. 4



ATTORNEY DOCKET No.: Beiersdorf 454-KGB
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COMBINATION DECLARATION & POWER OF ATTORNEY

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name,

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled

COSMETIC OR PHARMACEUTICAL MICROEMULSIONS

the specification of which

- ☐ is attached hereto.
- ☒ was filed on September 12, 1997 as application Serial No. 08/930,235.

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to the examination of this application in accordance with Title 37, Code of Federal Regulations §1.56(a).

I hereby claim foreign priority benefits under Title 35, United States Code, §119 of any foreign application(s) for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed:

Prior Foreign Application(s)			Priority Claimed
195 09 079.9 (Number)	Germany (Country)	15 March 1995 (Day/Month/Yr. Filed)	[X] yes [ ]no
_____ (Number)	_____ (Country)	_____ (Day/Month/Yr. Filed)	[ ] yes [ ]no

I hereby claim the benefit of 35 U.S.C. § 119(e) of any United States Provisional Application(s) listed below.

_____ (application number) _____ (filing date)

_____ (application number) _____ (filing date)

I hereby claim the benefit under Title 35, United States Code, §120 of any United States application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code, §112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, §1.56(a) which occurred between the filing date of the prior application and the national or PCT international filing date of this application:

(Application Serial No.)	(Filing Date)	(Status) (patented, pending, abandoned)

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punished by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

POWER OF ATTORNEY: As a named inventor, I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and transact all business in the Patent and Trademark Office connected therewith:

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